

Medicines and technologies programme

Patient group directions

NICE guideline

Methods, evidence and recommendations

March 2017

*Commissioned by the National Institute for
Health and Care Excellence*

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Contents

1	Introduction	6
1.1	Background and policy context	6
1.2	Legal framework	7
1.3	Terms used in the guideline	10
2	Development of a NICE guideline	11
2.1	What is a NICE guideline	11
2.2	Remit	11
2.3	Who developed the guideline	11
2.4	What this guideline covers	11
2.5	What this guideline does not cover	12
2.6	Related NICE guidance	12
3	Methods	13
3.1	Identifying the evidence	13
3.1.1	Literature searching	13
3.2	Reviewing the evidence	13
3.2.1	Inclusion and exclusion criteria	13
3.2.2	Types of evidence	13
3.3	Developing recommendations	14
3.3.1	Research recommendations	14
3.4	Validation process	14
3.5	Updating the guideline	14
4	Guideline summary	15
4.1	Recommendations	15
4.1.1	Considering the need for a patient group direction	15
4.1.2	Obtaining agreement to develop a Patient Group Direction	16
4.1.3	Developing Patient Group Directions	18
4.1.4	Authorising Patient Group Directions	18
4.1.5	Using Patient Group Directions	19
4.1.6	Reviewing and updating Patient Group Directions	21
4.1.7	Training and competency	22
4.1.8	Organisational governance	22
4.2	Overview of the process for considering the need for, developing, authorising, using and updating PGDs	24
5	Considering the need for a patient group direction	25
5.1	Evidence to recommendations	25
5.2	Recommendations and research recommendations	28
6	Obtaining agreement to develop a patient group direction	30
6.1	Evidence to recommendations	30

6.2	Recommendations and research recommendations	31
7	Developing patient group directions.....	34
7.1	Evidence to recommendations	34
7.2	Recommendations and research recommendations	36
8	Authorising patient group directions.....	37
8.1	Evidence to recommendations	37
8.2	Recommendations and research recommendations	39
9	Using patient group directions.....	41
9.1	Evidence to recommendations	41
9.2	Recommendations and research recommendations	42
10	Reviewing and updating patient group directions	44
10.1	Evidence to recommendations	44
10.2	Recommendations and research recommendations	45
11	Training and competency	46
11.1	Evidence to recommendations	46
11.2	Recommendations and research recommendations	48
12	Organisational governance	49
12.1	Evidence to recommendations	49
12.2	Recommendations and research recommendations	50
13	References	52
14	Glossary	53

1 Introduction

1.1 Background and policy context

Patient group directions (PGDs) provide a legal framework that allows the [supply](#) and/or [administration](#) of a specified medicine(s), by named, authorised, registered health professionals, to a pre-defined group of patients needing prophylaxis or treatment for a condition described in the PGD, without the need for a prescription or an instruction from a [prescriber](#).

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

‘Written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.’

This definition should not be interpreted as indicating that the patient should not be identified. Patients may or may not be known to the service provider (see [section 5](#)).

The [Health Service Circular \(HSC 2000/026\)](#) states that ‘the majority of clinical care should be provided on an individual, patient-specific basis’. Supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care without compromising patient safety, and there are clear governance arrangements and accountability. Using a PGD is not a form of prescribing.

Prescribing, supplying and administering medicines

Understanding the distinction between prescribing, supplying and administering medicines to patients is important for individual people and organisations involved with PGDs. There are no **legal** definitions that distinguish between prescribing, supplying and administering a medicine. See [glossary](#) for definitions used for the purpose of this guideline.

This traditional ‘medical model’ changed in the years after publication of the final Crown report [Review of prescribing, supply and administration of medicines](#) in 1999. Legal frameworks were developed that have allowed services to be redesigned and health professionals to work more flexibly for the benefit of patients. In particular, prescribing responsibilities have been extended to enable other health professionals to complete additional training and qualify as [non-medical prescribers](#). In addition, at some key steps in a care pathway, some of these frameworks enable medicines to be supplied and/or administered directly by a health professional, without the need for prescribing.

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

- Independent prescribing – the prescriber (a doctor, dentist or non-medical independent prescriber) takes responsibility for the clinical assessment of the patient, establishing a diagnosis, the clinical management needed and prescribing.
- [Supplementary prescribing](#) – a voluntary partnership between a doctor or dentist and a supplementary prescriber, to prescribe within an agreed patient-specific [clinical management plan](#) with the patient’s agreement.
- [Patient Specific Directions \(PSDs\)](#) – written instructions, signed by a doctor, dentist, or non-medical prescriber for a medicine to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis. Writing a PSD is a form of prescribing.
- [Patient Group Directions \(PGDs\)](#).

- Exemptions from medicines legislation, which are separate from prescribing and the arrangements for PGDs. A [full list of exemptions](#) is included in [The Human Medicines Regulations 2012](#). These include:
 - a range of exemptions enable certain groups of health professionals, such as chiropodists and podiatrists, midwives, paramedics and optometrists, to sell, supply and administer particular medicines directly to patients
 - occupational health schemes
 - [pandemic disease](#).These exemptions are distinct from prescribing and the arrangements for PGDs. A [full list of exemptions](#) is included in [The Human Medicines Regulations 2012](#).
- [Parenteral medicines](#) that can be administered in an emergency without the directions of a prescriber.
- [Emergency supplies](#) – in an emergency and under certain conditions, a pharmacist working in a registered pharmacy can supply a previously prescribed [prescription-only medicine](#) (POM) to a patient without a prescription, if requested by a [prescriber](#) or the [patient](#).

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

1.2 Legal framework

Legislation establishing PGDs was introduced in 2000 and the [Health Service Circular \(HSC 2000/026\)](#) provided additional guidance. The current legislation for PGDs is included in the [Human Medicines Regulations 2012](#), which came into force in August 2012. This [legislation was amended](#) in April 2013 to reflect changes to NHS organisational structures in England, as a result of the [Health and Social Care Act 2012](#).

Authorising patient group directions

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

PGDs must also be signed on behalf of the authorising body, as set out in the [Human Medicines Regulations 2012](#) (and subsequent amendments). In the NHS in England, the following organisations are authorising bodies:

- Clinical commissioning groups (CCGs)
- local authorities
- NHS trusts or NHS foundation trusts
- NHS England
- Public Health England.

See also sections [5](#) and [8](#).

Health professionals eligible to use patient group directions

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

- chiropodists and podiatrists
- dental hygienists
- dental therapists
- dietitians

- midwives
- nurses
- occupational therapists
- optometrists
- orthoptists
- orthotists and prosthetists
- paramedics
- pharmacists
- physiotherapists
- radiographers
- speech and language therapists.

Individual health professionals [must be named and authorised](#) to practice under a PGD. See also sections [5](#) and [11](#).

Medicines and healthcare products excluded from PGDs

Legislation requires that the following must not be included in a PGD:

- [unlicensed medicines](#), including:
 - the mixing of 2 [licensed medicines](#) to form 1 new (unlicensed) product, unless 1 is a vehicle for administration, such as water for injection
 - [special manufactured medicines](#)
- dressings, appliances and devices
- radiopharmaceuticals
- abortifacients, such as mifepristone.

Controlled drugs

Only certain controlled drugs are legally eligible to be included in a PGD, in accordance with [The Misuse of Drugs Regulations \(2001\)](#); see table 1.

Table 1: Controlled drugs that may be considered for inclusion in a PGD

Schedule	Controlled drugs that may be considered for inclusion in a PGD	Additional comments
Schedule 2	Morphine Diamorphine Ketamine	Use of morphine and diamorphine by registered nurses and pharmacists only, for the immediate necessary treatment of a sick or injured person (except for treating addiction)
Schedule 3	Midazolam	
Schedule 4	All drugs, including benzodiazepines	Anabolic steroids and any injectable preparation used for treating addiction must not be included in a PGD
Schedule 5	All drugs, including codeine	

See also [section 5](#).

Information to be included in a patient group direction

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

- ‘the period during which the direction is to have effect
- the description or class of medicinal product to which the direction relates
- the clinical situations which medicinal products of that description or class may be used to treat or manage in any form
- whether there are any restrictions on the quantity of medicinal product that may be sold or supplied on any one occasion and, if so, what restrictions
- the clinical criteria under which a person is to be eligible for treatment
- whether any class of person is excluded from treatment under the direction and, if so, what class of person
- whether there are circumstances in which further advice should be sought from a doctor or dentist and, if so, what circumstances
- the pharmaceutical form or forms in which medicinal products of that description or class are to be administered
- the strength, or maximum strength, at which medicinal products of that description or class are to be administered
- the applicable dosage or maximum dosage
- the route of administration
- the frequency of administration
- any minimum or maximum period of administration applicable to medicinal products of that description or class
- whether there are any relevant warnings to note and, if so, what warnings
- whether there is any follow up action to be taken in any circumstances and, if so, what action and in what circumstances
- arrangements for referral for medical advice
- details of the records to be kept of the supply, or the administration, of products under the direction’.

See also [section 7](#).

Other legislation

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

A manufacturer’s patient information leaflet [must be provided](#) to patients who have a medicine **supplied** under a PGD. This is not required by legislation when a medicine is **administered**.

[Legislation](#) relating to prescription charges and exemptions (including [pandemic influenza exemptions](#)) also applies to patients receiving a **supply** of medicine(s) [under a PGD](#) from the NHS. Prescription charges do not apply when medicines are **administered** under a PGD.

See also [section 9](#).

1.3 Terms used in the guideline

Authorising body

An organisation listed in the legislation (and subsequent amendments) that is legally able to authorise a PGD. The commissioning and/or provider organisation may be an authorising body.

In the NHS in England, these organisations are:

- clinical commissioning groups (CCGs)
- local authorities
- NHS trusts or NHS foundation trusts
- NHS England
- Public Health England.

Commissioning organisation/commissioner

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

Organisations

Unless stated otherwise, use of the term 'organisation' includes authorising bodies and any other organisations (both NHS and non-NHS) who are considering the need for, developing, authorising, using and updating PGDs to provide [public-funded services](#).

Patient group direction (PGD)

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

PGD approval group

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

PGD working group

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

Provider organisation/provider

The organisation responsible for providing the commissioned service, which may require the prescribing, supply or administration of medicines. This may be an NHS organisation or a non-NHS organisation providing public-funded service.

2 Development of a NICE guideline

2.1 What is a NICE guideline

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

2.2 Remit

NICE received the remit for this guideline from the Department of Health. NICE commissioned the NICE Medicines and prescribing centre (now the Medicines and technologies programme) to produce the guideline.

2.3 Who developed the guideline

A multidisciplinary Committee comprising health professionals and lay members developed this guideline (see appendix A for the list of Committee members). The Committee recognised that amendments to medicines legislation relating to PGDs were being prepared. The Committee agreed to invite a representative from the [Medicines and Healthcare products Regulatory Agency \(MHRA\)](#) to join the Committee as a co-opted member.

This NICE guideline was developed using the methodology described in the [NICE interim methods guide for developing good practice guidance](#).

The Committee met regularly during the development of the guideline. At the start of the guideline development process all Committee members declared interests including consultancies, fee-paid work, share-holdings, fellowships and support from the healthcare industry. The details of declared interests and the actions taken are shown in appendix A.

The NICE guideline developing team provided methodological support and guidance for the development process, including an assistant project manager, senior advisers, information scientists and a project lead. They undertook systematic searches of the literature, appraised the evidence and drafted the guideline in collaboration with the Committee.

2.4 What this guideline covers

This guideline has been developed to incorporate medicines legislation and takes into account the range of organisations providing public funded services. The guideline covers the legislation, systems and processes used when commissioners and providers of public-funded services are considering the need for, developing, authorising, using and updating PGDs. This includes NHS organisations, local authorities (in England), and any public-funded 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 Committee considered other options for supplying and/or administering medicines to patients (see [section 1.1](#)). However, recommendations have not been made in relation to these options.

2.5 What this guideline does not cover

Legislation, systems and processes relating to PGDs used to provide non-NHS healthcare services are not included in the scope of this guidance.

2.6 Related NICE guidance

Details are correct at the time of publication of the refreshed guideline (March 2017). Further information is available on the [NICE website](#).

2.6.1 Published NICE guidance

General

- [Controlled drugs: safe use and management](#) (2016) NICE guideline NG46
- [Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use](#) (2015) NICE guideline NG15
- [Medicines optimisation](#) (2015) NICE guideline NG5
- [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- [Service user experience in adult mental health](#) (2011) NICE guideline CG136
- [Medicines adherence](#) (2009) NICE guideline CG76

3 Methods

This chapter sets out the methods used to review the evidence and to generate the recommendations that are presented in subsequent chapters. This guideline was developed in accordance with the methods outlined in [NICE interim methods guide for developing good practice guidance](#).

3.1 Identifying the evidence

3.1.1 Literature searching

A literature search was undertaken based on the scope of the guidance (see appendix B 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.

3.2 Reviewing the evidence

The evidence retrieved from the search strategy was systematically reviewed. Evidence identified from the literature search was reviewed by title and abstract (first sift).

Full papers of the included studies were requested. All full text papers were then reviewed (second sift). The second sift included searching for relevant primary research that addressed the systems and processes used when commissioners and providers of public funded services are considering the need for developing, authorising, using and updating PGDs.

3.2.1 Inclusion and exclusion criteria

Selection of relevant studies was carried out by applying the exclusion criteria below:

- articles of limited or no relevance against search terms
- non-English language abstracts or non-English language articles with English abstract.

3.2.2 Types of evidence

Only evidence in the English language was considered.

No systematic reviews, randomised controlled trials or other types of studies were identified. Therefore, relevant legislation, guidance and policy were used to inform the development of this guideline (see [references](#)). After selection of the published evidence, the guideline developing team conducted a gap analysis. The Committee reviewed the evidence and the guideline developing team's gap analysis and decided that a call for evidence from the NHS was not needed.

The Committee recognised that NHS services are provided using PGDs in many different settings, including public-funded services provided by non-NHS organisations. Many of these settings, such as ambulance services and independent health providers, did not appear to be well represented in the published literature.

The Committee agreed that the recommendations would cover the principles for considering the need for, developing, authorising, using and updating PGDs, but these could not be tested out in all settings. However, the Committee concluded that the guideline developing team would make contacts with stakeholders from other settings, such as prison services to identify any issues specific to their setting. From the evidence submitted, no additional issues were identified that had not been considered by the Committee.

3.3 Developing recommendations

The recommendations have been developed by the Committee using relevant legislation, guidance and policy as the foundation for good practice (see [references](#)). Committee discussions were captured in the 'Linking evidence to recommendations' (LETR) table for each key area.

When a recommendation is aimed specifically at an individual person or organisation, this is clearly identifiable. However, in many cases, the Committee was not able to identify which individual person or organisation was responsible. This will be for commissioners and providers to consider and determine locally. The Committee agreed that arrangements will vary depending on local organisational structures, how services are commissioned and provided, and what resources are available.

Where evidence was of poor quality, conflicting or absent, the Committee drafted recommendations based on its expert opinion. Consensus based recommendations considered the balance between potential benefits and harms, economic costs compared with benefits, current practice, other guideline recommendations, patient preferences and equality issues, and were agreed through discussion with the Committee.

The wording of the recommendations took into account the strength of the evidence and wording was based on the [NICE interim methods guide for developing good practice guidance](#) principles; 'some recommendations are 'strong' in that the Committee believes if others (including health and social care professionals and patients) considered the evidence in the same way they would agree with the recommendations'. This is generally the case if the Committee is confident that, for the majority of people and organisations, the benefits from the recommended practice will outweigh any harm, represent good practice and is cost effective (if cost effectiveness has been assessed). Where the balance between benefit and harm is less clear cut, then the recommendations are 'weaker'; some people or organisations may choose to practice differently with similar benefits to that of the recommended practice. Recommendations for practice that 'must' or that 'must not' be followed are usually included only if there is a legal requirement to apply the recommendation, except occasionally when there are serious consequences of not following a recommendation (for example, if there is a high risk to patient safety).

See section 9 of [Developing NICE guidelines: the manual](#) for more information on developing and wording recommendations.'

3.3.1 Research recommendations

The Committee did not make any research recommendations.

3.4 Validation process

This guideline was subject to a 4-week public consultation. This allowed stakeholders, members of the public and other NICE teams to peer review the document as part of the quality assurance process. All comments received from registered stakeholders within the specified deadline were responded to. All comments received and responses given were posted on the NICE website (see section 13 of the [NICE interim methods guide for good practice guidance](#)).

3.5 Updating the guideline

The guideline will be updated in accordance with the process outlined in section 15 of [Developing NICE guidelines: the manual](#).

4 Guideline summary

When reviewing the evidence gathered for this guidance, the Committee concluded that the key principles in each of the following areas needed careful consideration:

- Considering the need for a patient group direction (PGD)
- Obtaining agreement to develop a PGD
- Developing PGDs
- Authorising PGDs
- Using PGDs
- Reviewing and updating PGDs
- Training and competency
- Organisational governance

An overview of the process agreed by the Committee for considering the need for, developing, authorising, using and updating a PGD is shown in [section 4.2](#). Details may vary depending on local organisational structures and how services are designed. Although this guidance is written in the context of the NHS in England, it also applies in Wales. The Committee agreed that the principles may also be applicable to individual people and organisations delivering non-public funded healthcare services, and to other devolved administrations.

4.1 Recommendations

Considering the need for a patient group direction

1. Provide the majority of clinical care involving supplying and/or administering medicines on an individual, patient-specific basis. Reserve [patient group directions \(PGDs\)](#) for limited situations in which this offers an advantage for patient care, without compromising patient safety, and where there are clear governance arrangements and accountability.
2. 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.
3. Use the [NHS Specialist Pharmacy Service PGD resources](#) 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.
4. Consider investing in the training of additional [non-medical prescribers](#) to enable redesign of services if necessary, as part of a wider development or review of local medicines policy.
5. PGDs must be used only by named and authorised registered health professionals who can legally supply and/or administer medicines using a PGD (see recommendation 36) in line with the [Human Medicines Regulations 2012](#).
6. PGDs must only include medicines with a UK marketing authorisation, in line with the [Human Medicines Regulations 2012](#).

7. Ensure that [off-label use](#) of a [licensed medicine](#) is included in a PGD only when clearly justified by best clinical practice. Clearly state that the medicine is being used outside the terms of the marketing authorisation on the PGD. Consider informing the patient or their carer that the use is off-label, in line with [General Medical Council guidance on prescribing unlicensed medicines](#).
8. Ensure that a [black triangle medicine](#) is included in a PGD only when clearly justified by best clinical practice. Clearly indicate the black triangle status on the PGD.
9. Ensure that a controlled drug is included in a PGD only when legally permitted and clearly justified by best clinical practice.
10. Do not jeopardise local and national strategies to combat antimicrobial resistance and [healthcare-associated infections](#). Ensure that an antimicrobial is included in a PGD only when:
 - clinically essential and clearly justified by best practice guidance
 - a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented (see recommendation 23)
 - use of the PGD is monitored and reviewed regularly (see recommendations 49 and 64).
11. Do not include a medicine needing frequent dosage adjustments or frequent or complex monitoring in a PGD (for example, anticoagulants or insulin).
12. Do not make dose adjustments to a medicine supplied under a PGD when the medicine is already in the patient's possession.
13. Carefully consider the risks and benefits of including more than 1 medicine in a PGD on a case-by-case basis. Ensure all legal requirements are met for each medicine in line with the [Human Medicines Regulations 2012](#).
14. Do not use PGDs for managing long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis.

Obtaining agreement to develop a patient group direction

15. Establish a robust and transparent process for obtaining the agreement of the [authorising body](#) before proceeding to develop a PGD. Ensure that relevant information is clear and easily accessible.
16. Ensure that a multidisciplinary [PGD approval group](#), with a locally defined mix of members, reviews proposals to develop PGDs. Define the roles and responsibilities of members and consider their training and competency needs.
17. Ensure that 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
 - declaring any conflicts of interests
 - setting the agenda of meetings and taking minutes or notes
 - prioritising PGD proposals

- **establishing reporting arrangements**
 - **engaging stakeholders, such as clinical groups and patients and the public**
 - **liaising with commissioning and finance.**
- 18. Ensure that the following information is included in proposal documentation for seeking 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 and/or administering 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.**
- 19. Establish a robust and transparent decision-making process that clearly defines standard criteria for reviewing 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**
 - **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 have been 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, such as finance, training, medicines procurement and diagnostic equipment are available for service delivery
 - adequate resources are available to ensure that processes are followed within any locally agreed timeframe
 - decisions are aligned with local clinical commissioning frameworks.
20. Record decisions to accept or reject the proposal, including the rationale for the decision. Communicate the decision by writing to the person who submitted the proposal, within a locally agreed timeframe. Ensure that the decision is communicated to other appropriate stakeholders.
21. 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.

Developing patient group directions

22. Ensure that a named lead author has responsibility for developing a PGD, supported by a locally determined multidisciplinary [PGD working group](#). Include a doctor (or dentist), pharmacist and representative of any other professional group(s) using the PGD. Define their roles and responsibilities, and consider their training and competency needs.
23. Liaise with a local specialist in microbiology when developing a PGD that includes an antimicrobial (see recommendation 10).
24. Seek views on draft PGDs and agree final draft PGDs with relevant stakeholders, including clinicians and local medicines decision-making groups.
25. All required information must be included in a PGD in line with the [Human Medicines Regulations 2012](#). Use a standard template to ensure that the format is consistent across the organisation.
26. Ensure PGDs are consistent with the relevant summary of product characteristics, unless the medicine is being used [off-label](#) or relevant national guidance is being followed (see recommendation 7).
27. Use the best available evidence, such as [NICE guidance](#) and other sources of high-quality information when developing PGDs. Include key references in an appendix to the PGD.

Authorising patient group directions

28. PGDs must be authorised only by an appropriate [authorising body](#) in line with the [Human Medicines Regulations 2012](#).
29. Address barriers that may delay authorising PGDs, such as lack of clear leadership, ownership and understanding of legislation and governance arrangements.

30. At an early stage, identify the appropriate senior doctor (or dentist) and senior pharmacist who will sign the PGD, in line with the [Human Medicines Regulations 2012](#). Define the roles and responsibilities of these people and consider their training and competency needs.
31. 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.
32. At an early stage, identify the appropriate person who will sign the PGD as a representative of any professional group(s) practising under the PGD. Consider their training and competency needs.
33. At an early stage, identify the appropriate person, such as the clinical governance or patient safety lead, who has designated responsibility for signing PGDs on behalf of the authorising body, in line with the [Human Medicines Regulations 2012](#). Define the roles and responsibilities of this person and consider their training and competency needs.
34. 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.
35. Assess local needs and develop a communications plan to support the dissemination of PGDs. Identify an appropriate person who is responsible for ensuring that this occurs.
36. For each PGD, the provider organisation should:
 - identify a senior, responsible person from within the service^a to authorise named, registered health professionals to practise under the PGD (see recommendation 5)
 - ensure that authorised health professionals have signed the appropriate documentation (see recommendation 40).
37. Publish final signed versions of PGDs on an intranet.
38. When a PGD is developed and authorised by a commissioning organisation for use across multiple provider organisations, ensure that it is adopted for use within each provider organisation.

Using patient group directions

39. When supplying and/or administering a medicine under a PGD, health professionals should follow local organisational policies and act within their code(s) of professional conduct and local governance arrangements (see recommendations 60 and 61).
40. Before practising under a PGD, health professionals should ensure that they:

^a If the provider is not the authorising body, this responsibility would require a formal agreement between the commissioner and provider

- have undertaken the necessary initial training and continuing professional development
- have been assessed as competent and authorised to practise by the [provider organisation](#) (see recommendation 36)
- have signed the appropriate documentation (see recommendation 36)
- are using a copy of the most recent and in date final signed version of the PGD (see recommendation 37)
- have read and understand the context and content of the PGD.

41. When practising under a PGD, health professionals should:

- not [delegate](#) their responsibility
- ensure that they can determine that the patient meets the inclusion criteria as set out in the PGD
- ensure that they can determine that no exclusion criteria apply
- 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, including maintenance of the 'cold chain'
 - follow-up arrangements
- be able to advise the patient or their carer about the medicine(s), as appropriate.

42. When supplying a medicine(s), provide an [appropriately labelled pack](#). Health professionals (other than pharmacists or dispensing doctors) should not split packs.

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

44. Identify whether patients supplied with a medicine(s) under a PGD are exempt from NHS prescription charges. The appropriate prescription charge(s) must be collected from patients who are not exempt, in line with [National Health Service \(Charges for Drugs and Appliances\) Amendment \(No. 2\) Regulations 2000](#).

45. 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 the patient met the criteria of the PGD

- details of medicine, such as name, strength, dose, frequency, quantity, route and site (if by injection) of administration (record the batch number and expiry date for vaccines, blood-derived products and other medicines if recommended by relevant national guidance)
- a statement that supply or administration is by using a PGD
- name and signature (which may be an electronic signature) of the health professional supplying or administering the medicine
- relevant information that was provided to the patient or their carer
- whether patient consent to treatment was obtained, in line with the [Department of Health's advice on consent](#) (2009).

Reviewing and updating patient group directions

46. Establish and manage a structured work programme for reviewing, updating and reauthorising PGDs. Ensure that sufficient resources are available to deliver the work programme.
47. Ensure that a named lead author has responsibility for reviewing and updating the PGD, supported by a locally determined multidisciplinary [PGD working group](#). Include a doctor (or dentist), pharmacist and representative of any other professional group(s) using the PGD. Define their roles and responsibilities and consider their training and competency needs (see recommendation 22).
48. When reviewing the PGD, conduct an appropriate literature search to identify new evidence. Ensure that this evidence is evaluated to assess its relevance and validity.
49. 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, such as patients or their carers.
50. Determine the expiry date for an individual PGD on a case-by-case basis, with patient safety paramount. Ensure that this date does not exceed 3 years from the date the PGD was authorised.
51. Ensure that an updated PGD is reauthorised, in line with the [Human Medicines Regulations 2012](#) (see recommendations 30 to 34).
52. When a PGD is updated, ensure all relevant documentation is also updated, including the record and signatures of health professionals authorised to practise under the PGD (see recommendation 65).
53. Ensure that an updated PGD is communicated and disseminated effectively to all relevant stakeholders (see recommendation 35 and 37).
54. 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

- 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.

Training and competency

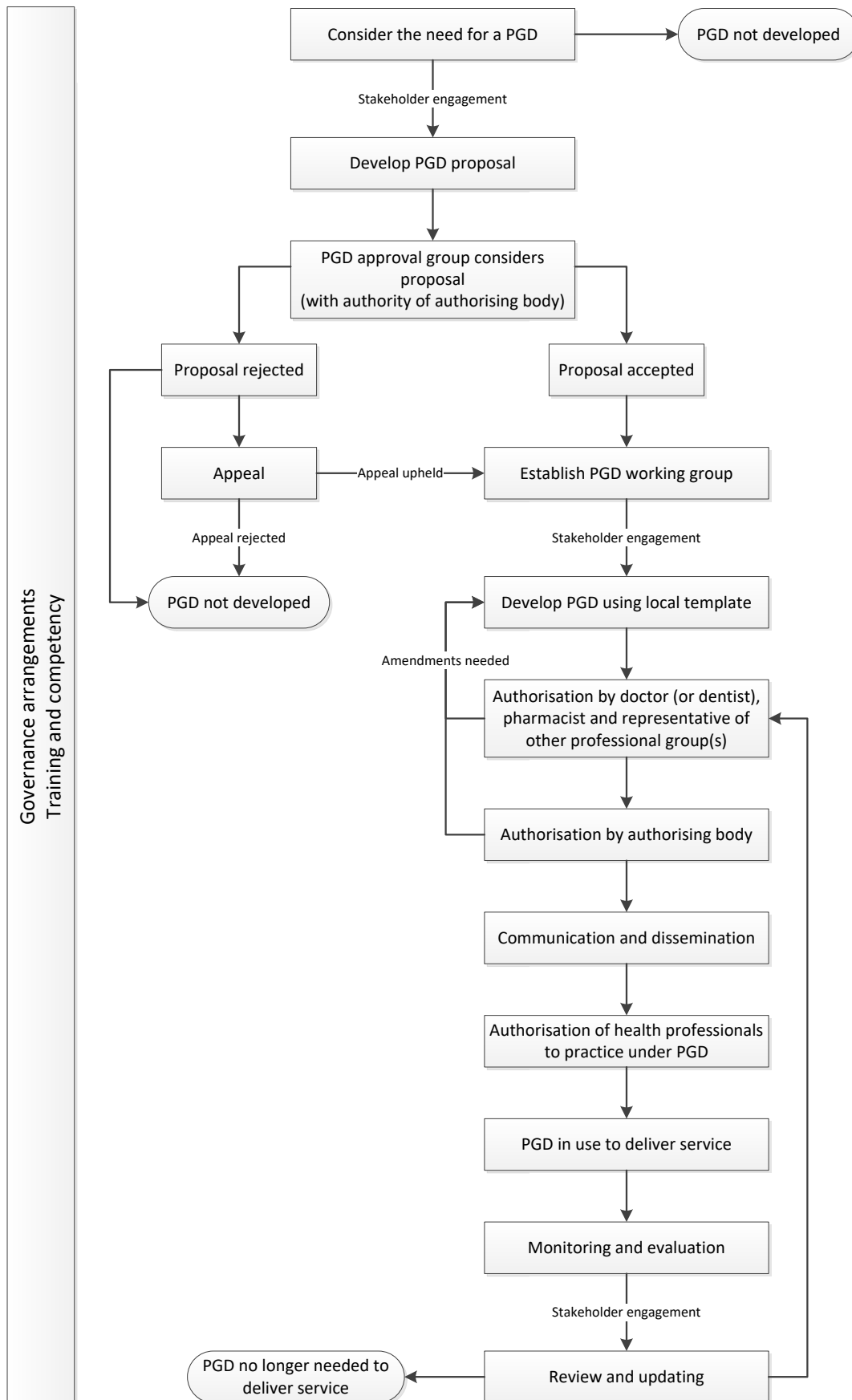
55. Identify the senior person in each profession who is responsible for ensuring that only fully competent, qualified and trained health professionals use PGDs.
56. Identify gaps in competency and establish a comprehensive and appropriate training programme for all people involved in considering the need for, developing, authorising, using and updating PGDs.
57. Ensure that adequate educational materials are available to enable individual people and [organisations](#) to deliver safe and effective services in which PGDs are used.
58. Consider collaborating with other organisations and sharing existing educational materials to ensure a comprehensive approach.
59. Ensure that training and re-training of health professionals using PGDs incorporates a post-training assessment of competency.

Organisational governance

60. For each PGD, the [commissioning](#) and [provider organisation\(s\)](#) should collaborate to firmly establish local governance arrangements with clear lines of responsibility and accountability.
61. Develop or review the organisational PGD policy and associated procedures to ensure that robust and transparent processes are documented. Ensure that the PGD policy is publicly available.
62. Ensure that a designated person has overall organisational responsibility for PGDs.
63. Ensure that [patient safety incidents](#) relating to PGD use are reported, collated and reviewed by the appropriate [organisations](#) in a planned programme, in line with national patient safety reporting systems.
64. Agree and undertake a planned programme of monitoring and evaluation of PGD use within the service.
65. Ensure that 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 should include:
 - patient safety incidents, such as medication errors, near misses and suspected adverse events
 - terms of reference and minutes or notes of the [PGD approval group](#)

- a list of all PGDs in use within the organisation, including their review date and expiry date
- master authorised copies of PGDs
- expired versions of PGDs
- members of the [PGD working group](#)
- signatures of people signing a PGD
- a list of named, registered health professionals authorised to practise under each PGD used within the service
- training records
- results of monitoring and evaluation.

4.2 Overview of the process for considering the need for, developing, authorising, using and updating PGDs



5 Considering the need for a patient group direction

5.1 Evidence to recommendations

Table 2: Linking evidence to recommendations (LETR)

The Committee agreed that when considering the need for a Patient Group Direction (PGD), it is important to recognise that prescribing or a Patient Specific Direction (PSD) remains the preferred option for the majority of care.

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

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

The Committee identified the importance of firmly establishing local governance arrangements between the [commissioning](#) and [glossary](#) organisation(s) with clear lines of responsibility and accountability for each PGD. This should be undertaken at the earliest opportunity when considering the need for a PGD to avoid possible delays in developing and delivering appropriate services (see [section 12](#)).

Exploring the options for supplying and/or administering medicines

The [Health Service Circular \(HSC 2000/026\)](#) states that ‘the majority of clinical care should be provided on an individual, patient-specific basis (see [section 1](#)). Even in circumstances in which it may be legally possible, the Committee agreed that a PGD may not be the preferred and safest approach to individual situations of providing patients with the medicine(s) they need.

The Committee was aware of PGDs being used to deliver a service when [independent prescribing](#), [supplementary prescribing](#) or a [Patient Specific Direction \(PSD\)](#) would be a more appropriate option, for example, when prescribers were not available at the required time. The Committee considered that barriers to developing [non-medical prescribing](#), such as a lack of allocated funding and staff commitment, may have contributed to the unnecessary or inappropriate development of PGDs.

The Committee found evidence that in some circumstances, different options for prescribing, supplying and/or administering medicines can be beneficial when used in combination, subject to the appropriate training and competencies. 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 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.
- A community pharmacist who may administer using a PGD as part of an NHS-commissioned enhanced service.

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

- accident and emergency departments
- ambulance services
- community pharmacies
- contraception and sexual health clinics
- minor injuries units
- walk-in centres
- out-of-hours services.

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

The Committee was aware of the [NHS Specialist Pharmacy Service \(SPS\) website PGD resources](#) to help identify when a PGD may be the most appropriate option. The Committee agreed that these resources should be used when considering the need for a PGD. The Committee agreed that, in general, the need for a PGD in a specific clinical situation should be considered locally. A comprehensive approach should include reviewing the care pathway and exploring **all** the options for prescribing, supplying and/or administering medicines.

The Committee concluded that prescribing or a PSD for an individual patient remains the preferred option for the majority of clinical care. PGDs should not be seen as a direct substitute for prescribing.

In circumstances in which there are insufficient prescribers, the Committee accepted that PGDs may be needed as a short-term interim option while non-medical independent prescribing is developed, if that is the preferred approach. However, the Committee agreed that governance arrangements would need to be in place to ensure PGDs are used appropriately (see [section 12](#)). In addition, organisations may need to develop or review their strategic medicines policy to develop non-medical prescribing locally.

Health professionals eligible to use patient group directions

The Committee noted that [legislation](#) requires that only specific registered health professionals can use PGDs (see [section 1](#)). Most of the evidence identified from the literature search related to PGD use by nurses and pharmacists.

The Committee was aware of examples of other groups of healthcare workers using PGDs who were not eligible, such as healthcare assistants, student health professionals and registered health professionals [not listed in PGD legislation](#). Because this is not within the legal requirements for PGDs, the Committee agreed that organisations should identify and address any such practice when developing or reviewing their strategic medicines policy.

The Committee was also aware that [legislation](#) requires that registered health professionals using PGDs can only do so as named, authorised individuals and are not able to [delegate](#) their responsibility to another person (see [section 9](#)).

Organisations using patient group directions

The Committee was aware of the range of organisations and services that currently use PGDs to provide [public-funded](#) care. These are:

- NHS trusts and foundation trusts
- public-funded services including:
 - services provided by the private, voluntary or charitable sectors
 - urgent care services, such as out-of-hours services and walk-in centres
 - services provided by independent contractors, such as GP and dental practices and community pharmacies.

Medicines that can be considered for a patient group direction

The Committee was aware of legislation governing which medicines can be included in a PGD (see [section 1](#)). The Committee also reviewed the evidence and considered the

appropriateness of other medicines that may be considered for supply and/or administration using a PGD.

The Committee agreed that [off-label use](#) of a [licensed medicine](#) may be considered only when such use is clearly justified and supported by best clinical practice, such as national guidance from the [Joint Committee on Vaccination and Immunisation \(JCVI\)](#). Health professionals should consider informing patients about the licence for their medicines, in line with [prescribing guidance](#) published by the [General Medical Council](#) (2013).

The Committee also agreed that [black triangle medicines](#) may be considered only when such use is clearly justified and supported by best clinical practice, such as [NICE guidance](#).

Antimicrobial resistance and [healthcare-associated infections \(HCAI\)](#) are matters of major importance to public health. Organisations should ensure that they do not jeopardise local and national strategies to combat this threat. The Committee recognised that it may be appropriate to include an antimicrobial in a PGD in some circumstances, such as treating chlamydia in a sexual health clinic. However, it agreed that in most circumstances, PGDs are not appropriate for supplying and/or administering antimicrobials. The Committee concluded that antimicrobials should be included in a PGD only when:

- clinically essential and clearly justified by best practice guidance
- a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented
- use of the PGD is monitored and reviewed regularly (see [section 10](#)).

The Committee recognised that [specifying a range of doses](#) so the health professional could select the correct dose to supply or administer to a patient was appropriate in a PGD. For example, selecting the correct dose of an intra-articular methylprednisolone injection depending on the size of the affected joint.

The Committee was aware that PGD legislation relates only to the supply and/or administration of medicines. A health professional is not able to adjust the dose of a medicine without also supplying the medicine at the time of the dose adjustment. Therefore, the Committee noted that dose adjustments to a medicine supplied under a PGD must not be made when the medicine is already in the patient's possession.

In addition, the Committee did not consider frequent individual adjustment of dosage using a PGD to represent good practice and agreed that prescribing or a PSD would be a more appropriate option. The Committee agreed that the original intention of PGDs was not to include medicines needing frequent dose adjustments, or frequent or complex monitoring. The Committee supported the original intention and agreed that the risks of using these medicines in a PGD outweighed the benefits and alternative options should be used.

The Committee found evidence that more than 1 medicine **could** be included in a PGD. However, the Committee agreed that good practice was likely to be represented by including a single medicine. It recognised that including more than 1 medicine may be appropriate in some circumstances, provided all [legal requirements](#) were included for each medicine. The Committee concluded that the risks and benefits of including more than 1 medicine in a PGD should be carefully considered on a case-by-case basis.

The Committee heard reports of PGDs being used when a PGD is not needed, for example, when medicines are classified as [General Sales List \(GSL\)](#) or because of exemptions in legislation for specified medicines for certain groups of health professionals (see [section 1](#)). [Pharmacy \(P\) medicines](#) can also be supplied through registered pharmacies without the need for a PGD. See the [NHS Specialist Pharmacy Service \(SPS\) website PGD resources](#) for more information.

The Committee agreed that when a PGD is not necessary, a local protocol would be more appropriate, with the employing organisation retaining legal responsibility for the actions of its employees.

The Committee agreed examples of clinical situations when PGDs may be appropriate, These include when:

- medicine use follows a predictable pattern, such as for people attending for contraception
- patients seek unscheduled care, such as for a minor ailment in a community pharmacy or walk-in centre
- supplying or administering a medicine for a discrete treatment episode, such as emergency contraception
- there is a homogenous patient group, such as at-risk groups of patients needing immunisation.

The Committee agreed examples of clinical situations in which PGDs need to be considered carefully. These include 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 antimicrobial
- 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).

The Committee agreed examples of clinical situations in which alternatives to PGDs should be used. These include when;

- managing long-term conditions, such as hypertension or diabetes
- uncertainty remains about the differential diagnosis, particularly when further investigations or diagnostic tests are needed, for example erectile dysfunction
- the medicine needs frequent dosage adjustments, or frequent or complex monitoring, for example anticoagulants or insulin.

5.2 Recommendations and research recommendations

1. **Provide the majority of clinical care involving supplying and/or administering medicines on an individual, patient-specific basis. Reserve [patient group directions \(PGDs\)](#) for limited situations in which this offers an advantage for patient care, without compromising patient safety, and where there are clear governance arrangements and accountability.**
2. **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.**
3. **Use the [NHS Specialist Pharmacy Service PGD resources](#) 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.**
4. **Consider investing in the training of additional [non-medical prescribers](#) to enable redesign of services if necessary, as part of a wider development or review of local medicines policy.**

5. PGDs must be used only by named and authorised registered health professionals who can legally supply and/or administer medicines using a PGD (see recommendation 36) in line with the [Human Medicines Regulations 2012](#).
6. PGDs must only include medicines with a UK marketing authorisation, in line with the [Human Medicines Regulations 2012](#).
7. Ensure that [off-label use](#) of a [licensed medicine](#) is included in a PGD only when clearly justified by best clinical practice. Clearly state that the medicine is being used outside the terms of the marketing authorisation on the PGD. Consider informing the patient or their carer that the use is off-label, in line with [General Medical Council guidance](#).
8. Ensure that a [black triangle medicine](#) is included in a PGD only when clearly justified by best clinical practice. Clearly indicate the black triangle status on the PGD.
9. Ensure that a controlled drug is included in a PGD only when legally permitted and clearly justified by best clinical practice.
10. Do not jeopardise local and national strategies to combat antimicrobial resistance and [healthcare-associated infections](#). Ensure that an antimicrobial is included in a PGD only when:
 - clinically essential and clearly justified by best practice guidance
 - a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented (see recommendation 23)
 - use of the PGD is monitored and reviewed regularly (see recommendations 49 and 64).
11. Do not include a medicine needing frequent dosage adjustments or frequent or complex monitoring in a PGD (for example, anticoagulants or insulin).
12. Do not make dose adjustments to a medicine supplied under a PGD when the medicine is already in the patient's possession.
13. Carefully consider the risks and benefits of including more than 1 medicine in a PGD on a case-by-case basis. Ensure all legal requirements are met for each medicine in line with the [Human Medicines Regulations 2012](#).
14. Do not use PGDs for managing long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis.

6 Obtaining agreement to develop a patient group direction

6.1 Evidence to recommendations

Table 3: Linking evidence to recommendations (LETR)

The Committee found evidence that PGDs need significant resources and are time-consuming to produce. Some organisations had processes in place to obtain the agreement of the [authorising body](#) for the PGD before proceeding to develop the PGD. In other organisations, this step did not appear to be included in the process.

Submitting proposals to develop a patient group direction

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

The Committee agreed that proposal documentation for seeking the agreement of the authorising body to develop a PGD should include the following information:

- 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.

The Committee indicated that the PGD approval group should include the following people:

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

If additional expertise is needed, other professionals who may be invited include:

- specialists with appropriate expertise to provide clinical advice in a specific area, such as a local specialist in microbiology (for PGDs containing an antimicrobial) or a paediatric specialist (for PGDs to be used for treatment in children)
- lead practitioner in the area in which the PGD is to be used
- patient and public representative

- controlled drugs accountable officer (if the PGD includes a controlled drug)
- service commissioner or provider, depending on local governance arrangements, such as a local authority representative
- finance representative.

Process for reviewing proposals to develop a patient group direction

The Committee found evidence that the functions of the PGD approval group were often fulfilled by an existing local medicines decision-making group, such as a drug and therapeutics committee, or a subgroup. It agreed that the PGD approval group did not have to be a separate medicines decision-making group and may operate virtually or through face-to-face meetings.

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

- ensuring PGDs are not developed without previous agreement
- prioritising proposals to develop a PGD
- seeking the views of stakeholders on proposals, for example, from clinical groups, patients and the public, and the [commissioning](#) or [provider](#) organisation(s)
- gathering intelligence about local service delivery and exploring all the options for prescribing, supplying and/or administering medicines in a specific situation (see [section 5](#))
- considering the [arrangements](#) for the security, storage, packaging and labelling of medicines
- considering the resources needed to deliver the service, such as medicines procurement from a licensed manufacturing unit and any diagnostic equipment
- engaging with finance and commissioning to align decisions within the framework of clinical commissioning
- considering the resources, training and competencies needed for developing, authorising, using, monitoring, reviewing and updating the PGD (see [section 11](#))
- ensuring decision-making is robust and transparent with final decisions on proposals formally recorded and communicated to appropriate stakeholders.

The Committee concluded that an effective PGD approval group should be in operation with the delegated authority of the authorising body. There should be clear lines of governance, reporting arrangements and accountability, such as terms of reference, conflicts of interests, decision-making criteria and appropriate documentation. Proposals to develop a PGD should only be accepted if they comply with all legal requirements and professional guidance. Furthermore, the Committee agreed that clinical leads submitting proposals for developing PGDs should have the opportunity to appeal a decision that is not in their favour should they wish (see [section 4.2](#)). The appeals process should be clearly documented, including timescales for appeal, and this should be published on the organisation's intranet.

The Committee was also aware that multiple PGDs had been developed by different teams for the use of the same medicine in the same patient group across a single organisation. The Committee agreed that a single PGD in a patient group covering different services in 1 organisation would in most circumstances be more appropriate. The Committee concluded that operating a PGD approval group may help to reduce unnecessary duplication of PGDs.

6.2 Recommendations and research recommendations

15. Establish a robust and transparent process for obtaining the agreement of the [authorising body](#) before proceeding to develop a PGD. Ensure that relevant information is clear and easily accessible.

- 16. Ensure that a multidisciplinary [PGD approval group](#), with a locally defined mix of members, reviews proposals to develop PGDs. Define the roles and responsibilities of members and consider their training and competency needs.**
- 17. Ensure that 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
 - declaring any conflicts of interests
 - setting the agenda of meetings and taking minutes or notes
 - prioritising PGD proposals
 - establishing reporting arrangements
 - engaging stakeholders, such as clinical groups and patients and the public
 - liaising with commissioning and finance.
- 18. Ensure that the following information is included in proposal documentation for seeking 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 and/or administering 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.
- 19. Establish a robust and transparent decision-making process that clearly defines standard criteria for reviewing 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

- 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 have been 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, such as finance, training, medicines procurement and diagnostic equipment are available for service delivery
 - adequate resources are available to ensure that processes are followed within any locally agreed timeframe
 - decisions are aligned with local clinical commissioning frameworks.
20. Record decisions to accept or reject the proposal, including the rationale for the decision. Communicate the decision by writing to the person who submitted the proposal, within a locally agreed timeframe. Ensure that the decision is communicated to other appropriate stakeholders.
21. 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.

7 Developing patient group directions

7.1 Evidence to recommendations

Table 4: Linking evidence to recommendations (LETR)

The Committee agreed that development of a PGD should not proceed until the [PGD approval group](#), with the delegated authority of the [authorising body](#), has formally agreed that a PGD is needed (see [section 6](#)).

Responsibilities for developing patient group directions

The Committee agreed that either the [commissioner](#) or [provider](#) organisation may have responsibility for developing the PGD. This will be for commissioners and providers to consider and determine locally (see [section 12](#)). A number of scenarios may exist for developing and authorising PGDs, these may be:

Scenario 1: A commissioning organisation, such as a clinical commissioning group (CCG) may develop and authorise PGDs for use across several provider organisations, such as several community health services providers.

Scenario 2: An independent provider organisation may enter into arrangements to deliver a [public-funded](#) service using PGDs, but is not able to develop or authorise the PGD independently of the commissioning organisation. This may be because the provider organisation does not have the resources needed to develop PGDs and may not have the legal authority to authorise PGDs.

Scenario 3: An independent provider (such as an independent medical agency) or a commissioning support unit (CSU) may have the resources needed to develop PGDs, but may not have the legal authority to authorise the PGD.

Scenario 4: A provider organisation, such as an NHS trust, may develop and authorise its own PGDs to provide public-funded service.

Scenario 5: A commissioning or provider organisation may be an authorising body and have the legal authority to authorise a PGD, but may not have the resources needed to develop the PGD. In these circumstances, the necessary resources may need to be commissioned.

Process for developing patient group directions

Legislation does not specify who must be involved in developing PGDs. The [Health Service Circular \(HSC 2000/026\)](#) states that PGDs 'should be drawn up by a multidisciplinary group involving a doctor, a pharmacist and a representative of any other professional group expected to supply medicines under the PGD'.

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

The lead author may be a doctor (or dentist), pharmacist or representative of any other professional group who will practise under the PGD, or another person such as the service lead. The roles and responsibilities of each person, how they work together to develop the PGD and how the group operates should be determined locally and clearly defined.

A PGD working group should be established for each individual PGD (see [section 4.2](#)), although the same group may be responsible for developing a number of PGDs. The PGD working group is separate from, but would need to liaise with, the PGD approval group (see [section 6](#)).

The Committee agreed that members of the PGD working group developing a PGD should include:

- a lead author
- a doctor (or dentist)

- a pharmacist
- a representative of any other professional group who will practise under the PGD, such as a nurse.

The Committee recognised that in some organisations, particularly larger organisations, these members may not be the same people who sign the PGD as part of the authorisation process (see [section 8](#)). However, in other organisations, such as in small organisations with fewer resources, the PGD may be signed by the same people who were involved in developing the PGD.

The Committee concluded that whatever local arrangements are in place, the expertise of a doctor (or dentist), pharmacist and representative of any other professional group who will practise under the PGD is needed when developing a PGD (see [section 7](#)).

If additional expertise is needed, other professionals who may be involved in developing a PGD include:

- a specialist with appropriate expertise, such as a local [specialist in microbiology for PGDs containing an antimicrobial](#) (see [section 5](#))
- the people responsible for ensuring that only fully trained and competent professionals work under the PGD (see [section 11](#)).

The Committee recognised that people needed to develop PGDs may not all be available in the organisation responsible for developing the PGD. The Committee concluded that in these circumstances the authorising body should have clear governance arrangements in place to ensure that people in the PGD working group have the necessary knowledge, skills and expertise to develop PGDs (see [section 11](#)).

Evidence also suggested that the training and competency of people involved in developing PGDs was an important factor for local consideration (see [section 11](#)).

The Committee concluded that it was good practice for commissioning and provider organisations to collaborate when developing PGDs. Other relevant stakeholders are likely to include clinicians and other local medicines decision-making groups. Examples of collaboration may include:

- identifying specialist expertise for a PGD working group
- seeking views on a draft PGD and incorporating relevant suggestions
- agreeing a final draft PGD before it is submitted for authorisation (see [section 8](#)).

Presentation and content of patient group directions

The Committee found many examples of local PGD templates that are in use. It was aware that legislation requires that specific information must be included in a PGD for it to be legally valid (see [section 1](#)). The Committee concluded that the style, format and presentation of the PGD should be determined locally, but this should be consistent across the organisation and contain all the [legally required information](#).

The Committee was aware that some organisations have adapted existing PGDs developed by other organisations for their own use. The Committee agreed that organisations considering adapting an existing PGD should be assured that robust and transparent processes were followed in the development of the original PGD. Any organisation adapting an existing PGD for authorisation and use in their own organisation takes full responsibility and accountability for the content of the PGD (see [section 8](#)).

The [Health Service Circular \(HSC 2000/026\)](#) highlights the importance of ensuring that the use of a medicine(s) included in a PGD is consistent with the relevant [summary of product characteristics \(SPC\)](#), unless the medicine is being used [off-label](#) or relevant national guidance, such as [Joint Committee on Vaccination and Immunisation \(JCVI\)](#) or [NICE guidance](#) is being followed. Updates to the PGD may be needed following changes to the SPC (see [section 10](#)).

The Committee agreed that the process for developing a PGD should include conducting an appropriate literature search. The evidence identified should then be evaluated to assess its relevance and validity. The [Health Service Circular \(HSC 2000/026\)](#) also advises that the use of any medicine in a PGD is consistent with any relevant [NICE guidance](#). The Committee agreed that all relevant evidence used to develop the PGD should be referenced, such as the SPC or NICE guidance, and key references included in an appendix to the PGD.

Evidence suggests that PGDs should be reviewed every 2 years. However, the Committee agreed that the review period should be considered on a case-by-case basis when developing, reviewing and updating the PGD (see [section 10](#)).

7.2 Recommendations and research recommendations

22. Ensure that a named lead author has responsibility for developing a PGD, supported by a locally determined multidisciplinary [PGD working group](#). Include a doctor (or dentist), pharmacist and representative of any other professional group(s) using the PGD. Define their roles and responsibilities, and consider their training and competency needs.
23. Liaise with a local specialist in microbiology when developing a PGD that includes an antimicrobial (see recommendation 10).
24. Seek views on draft PGDs and agree final draft PGDs with relevant stakeholders, including clinicians and local medicines decision-making groups.
25. All required information must be included in a PGD in line with the [Human Medicines Regulations 2012](#). Use a standard template to ensure that the format is consistent across the organisation.
26. Ensure PGDs are consistent with the relevant summary of product characteristics, unless the medicine is being used [off-label](#) or relevant national guidance is being followed (see recommendation 7).
27. Use the best available evidence, such as [NICE guidance](#) and other sources of high-quality information when developing PGDs. Include key references in an appendix to the PGD.

8 Authorising patient group directions

8.1 Evidence to recommendations

Table 5: Linking evidence to recommendations (LETR)

The Committee noted that legislation requires that:

- a PGD must be signed by a doctor (or dentist) and a pharmacist
- a PGD must be signed on behalf of the authorising body
- health professionals who will be using the PGD must be named and authorised to practise under it.

An overview of the process agreed by the Committee for considering the need for, developing, authorising, using and updating a PGD is shown in [section 4.2](#).

Responsibilities for authorising patient group directions

The Committee discussed how healthcare is changing in the way it is delivered, with increasing use of independent providers, such as community service providers who are social enterprises, to deliver NHS services. Local authorities have taken on responsibility for some public health services, such as some sexual health services and smoking cessation. The Committee agreed that lines of accountability between the commissioning and provider organisation are at risk of becoming blurred. The Committee was also aware of lengthy delays experienced by some provider organisations in obtaining authorisation for a PGD from the commissioner (for example, out-of-hours service providers). The Committee was also aware that a provider organisation may deliver NHS-commissioned services using PGDs, but may not be able to develop or authorise PGDs independently of the commissioning organisation (see [section 7](#)). For example, independent hospitals and independent medical agencies cannot legally authorise PGDs to provide NHS-commissioned services. The Committee recognised that in some circumstances, both the commissioning and provider organisation may be an authorising body. If the provider is an authorising body, the commissioning organisation does not legally need to authorise the PGDs for the provider. However, this should have been identified when considering the need for a PGD to deliver the service (see [section 5](#)). The Committee was aware of the complexity in this area. It concluded that arrangements for authorising each PGD should be considered and determined locally by the commissioner and provider (see [section 12](#)). In addition, organisations may in some circumstances need to review whether their historic authorisation process is in line with current legislation.

The Committee concluded that whatever arrangements are agreed for authorising a PGD, the commissioner and provider have a joint responsibility to ensure that this is within the legal framework, and governance arrangements are in place and remain so for each PGD (see [section 12](#)). The Committee agreed that even when providers may be legally able to authorise PGDs, they may not have the necessary resources or expertise available.

People signing the patient group direction

When signing the PGD, the doctor (or dentist) and pharmacist take joint responsibility and accountability for the accuracy of both the clinical and pharmaceutical content of the PGD. The Committee agreed that this should be undertaken by senior professionals with full consideration of the clinical service in which the PGD is to be used (see [section 11](#)). The Committee recognised that the doctor (or dentist) and pharmacist signing the PGD may also be involved in developing the PGD (see [section 7](#)).

Evidence suggests that a clinical governance or patient safety lead in an NHS organisation would usually be responsible for signing PGDs on behalf of the authorising body. This person has responsibility for ensuring PGDs are developed in line with legislation (see [section 1](#)) and local organisational policies and governance arrangements, with full consideration of the service in which the PGD is to be used.

The Committee recognised that the decision to authorise PGDs may be undertaken by the [PGD approval group](#) or other locally determined medicines decision-making group.

Nevertheless, an individual person should have designated responsibility for signing PGDs on behalf of the authorising body.

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

The Committee discussed evidence that PGDs should also be signed by a representative of any other professional group(s) expected to supply and/or administer the medicine(s) under the PGD. The GDG agreed that although this is not required by legislation, this would continue to constitute good practice.

The Committee also found evidence that PGDs may be developed for use across multiple organisations. For example, a commissioning support unit (CSU) may develop a PGD for use across several clinical commissioning groups (CCGs). In this situation, the PGD would still need to be authorised within each CCG, because CSUs are not authorising bodies (see [section 7](#)).

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

In its review of the evidence, the GDG was aware that a PGD should be reauthorised after review and updating by the appropriate people:

- a doctor (or dentist)
- a pharmacist
- a representative of any other professional group(s) expected to supply and/or administer the medicine(s) under the PGD
- a person responsible for signing the PGD on behalf of the authorising body.

This reauthorisation process should occur even when a review results in minimal or no changes (see [section 4.2](#) and [10](#)).

The Committee concluded that authorising bodies need to consider the knowledge, skills and expertise needed by people who are authorising PGDs and ensure that they are aware of their responsibilities and can demonstrate their competency (see [section 11](#)).

Adopting the patient group direction within the service

When the PGD has been signed by the appropriate people and is authorised for use, clear local arrangements are needed that outline the ownership of, and responsibility for, delivering the service. The PGD may need to be 'adopted' by the provider organisation(s) if they have not been involved in developing and authorising the PGD (see [section 4.2](#)). For example, when a PGD is developed and authorised by a CCG for use across multiple GP practices, a process would need to be in place for each GP practice to adopt the PGD for use in their practice.

The Committee was aware that some commissioning organisations may ask the provider to co-sign their authorised PGDs to demonstrate that the provider has accepted their responsibility, for example, for authorising health professionals, training and competency assessment and the monitoring and evaluation of PGD use (see sections [11](#) and [12](#)). The Committee agreed that this would need to be determined locally and clearly defined within local governance arrangements.

The Committee recognised that organisations need to consider how the authorised PGD is communicated and disseminated effectively to all relevant stakeholders, for example, to the commissioning organisation if the provider has developed and authorised the PGD. The Committee agreed that organisations should publish final signed versions of PGDs on an intranet to allow named, authorised health professionals using the PGD to be able to access the most up-to-date version.

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

Eligible health professionals who will be using the PGD [must be named and authorised](#) to practise under it. The Committee agreed that provider organisations should designate an appropriate person (for example, a clinical supervisor, line manager or GP) to be responsible for authorising these health professionals in each service. A record of all the health professionals authorised to practise under the PGD should be maintained in the service (see [section 12](#)). In addition, authorised health professionals should sign the appropriate documentation as an agreement to practise within the requirements of the PGD and provide assurances that they are trained and competent to do so (see [section 9](#)).

The Committee concluded that when the employing provider organisation is not the authorising body, the responsibility for authorising health professionals to practise under the PGD would require a formal agreement between the commissioner and provider. This may be outlined in a [service level agreement](#) or [contract specification](#) (see [section 12](#)). Clear governance arrangements should be in place to ensure that only health professionals who have been trained and assessed as competent are authorised to practise under a PGD (see [section 11](#)).

8.2 Recommendations and research recommendations

28. PGDs must be authorised only by an appropriate [authorising body](#) in line with the [Human Medicines Regulations 2012](#).
29. Address barriers that may delay authorising PGDs, such as lack of clear leadership, ownership and understanding of legislation and governance arrangements.
30. At an early stage, identify the appropriate senior doctor (or dentist) and senior pharmacist who will sign the PGD, in line with the [Human Medicines Regulations 2012](#). Define the roles and responsibilities of these people and consider their training and competency needs.
31. 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.
32. At an early stage, identify the appropriate person who will sign the PGD as a representative of any professional group(s) practising under the PGD. Consider their training and competency needs.
33. At an early stage, identify the appropriate person, such as the clinical governance or patient safety lead, who has designated responsibility for signing PGDs on behalf of the authorising body, in line with the [Human Medicines Regulations 2012](#). Define the roles and responsibilities of this person and consider their training and competency needs.
34. 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.

- 35. Assess local needs and develop a communications plan to support the dissemination of PGDs. Identify an appropriate person who is responsible for ensuring that this occurs.**
- 36. For each PGD, the provider organisation should:**
 - **identify a senior, responsible person from within the service^b to authorise named, registered health professionals to practise under the PGD (see recommendation 5)**
 - **ensure that authorised health professionals have signed the appropriate documentation (see recommendation 40).**
- 37. Publish final signed versions of PGDs on an intranet.**
- 38. When a PGD is developed and authorised by a commissioning organisation for use across multiple provider organisations, ensure that it is adopted for use within each provider organisation.**

^b If the provider is not the authorising body, this responsibility would require a formal agreement between the commissioner and provider

9 Using patient group directions

9.1 Evidence to recommendations

Table 6: Linking evidence to recommendations (LETR)

The Committee noted that PGDs must only be used by registered health professionals listed in the [legislation](#). In addition, individual health professionals must be named on the PGD documentation and be [authorised to practise](#) under the PGD by their employing organisation (see [section 8](#)). The Committee was aware that some health professionals who work for different [provider organisations](#) must be authorised within each organisation.

Health professionals using patient group directions

The Committee was aware that health professionals who are eligible to work under a PGD require no additional formal qualification. However, health professionals have a professional responsibility to work within their competency and undertake appropriate professional development, to work safely with PGDs as part of their professional practice. They should adhere to local organisational policies and governance arrangements. In addition, the [Health Service Circular \(HSC 2000/026\)](#) states that 'all professions must act within their appropriate code of professional conduct'. Organisations should also ensure that appropriate training is available for health professionals using PGDs (see [section 11](#)). However, individual health professionals are responsible and accountable for their decisions to supply and/or administer medicines using a PGD.

Evidence discussed by the Committee showed that even when a PGD is available for use, it may not be appropriate to use it in every clinical situation. Health professionals authorised to use a PGD need to make an informed decision about whether the PGD is appropriate for an individual patient. This includes recognising when an alternative intervention is preferred and when signposting or referral to another health professional or provider is needed. For example, a patient may meet the requirements of a PGD for nicotine replacement therapy, but after discussion of the available options, may prefer the option of varenicline.

When using a PGD, health professionals must ensure that the patient meets the criteria exactly, as determined by the PGD. If the patient does not meet the criteria, or the health professional is not able to determine that they meet the criteria, the patient must be referred to another health professional or provider. The Committee noted that [legislation](#) states that these steps must be outlined in the PGD.

Individual health professionals are responsible for ensuring that they are practising under a PGD that is in date and the most recent version (see [section 8](#)). Organisations should ensure that PGDs in use are reviewed and updated, and this is communicated to health professionals and other relevant stakeholders (see [section 10](#)).

Medicines management systems

The Committee was aware that [prescription-only medicines \(POMs\) supplied to patients under a PGD](#) must contain the same labelling and other information that patients would otherwise receive if the medicine had been supplied against a prescription (see [section 1](#)). The Committee agreed that local arrangements should ensure that medicines supplied under a PGD should be in an [appropriately labelled pack](#). The Committee was aware that legislation enables pharmacists to split original packs when dispensing a medicine against a prescription. However, the Committee agreed that **all** health professionals (other than pharmacists or dispensing doctors) supplying medicines under a PGD should not split original packs into smaller units.

In addition, health professionals need to be aware of any storage requirements, such as maintenance of the 'cold chain' and ensure medicines are stored safely.

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

The Committee recognised that medicines supplied to patients under a PGD are subject to the payment of NHS prescription charges, unless exemptions apply. The Committee was aware that medicines that are administered are not subject to these charges. The Committee was aware that in some circumstances, the administrative burden of collecting NHS prescription charges appeared to be a barrier. However, the Committee concluded that local provider organisations must make arrangements for collecting the appropriate charges when medicines are **supplied** using a PGD, in line with [legislation](#). Health professionals should also ensure that NHS prescription charges are collected, when this is appropriate.

Documentation by health professionals using patient group directions

In its review of the evidence, the Committee noted that documentation relating to supplying and/or administering medicines under a PGD was often cited as an area for improvement. It recognised the importance of appropriate documentation when using PGDs and agreed that it would be good practice to document the following details:

- date and time of supply and/or administration
- patient details, such as name, date of birth, allergies, previous adverse events and how the patient met the criteria of the PGD
- details of medicine, such as name, strength, dose, frequency, quantity, route and site (if by injection) of administration; the batch number and expiry date should also be recorded for vaccines, blood-derived products and other medicines if recommended by relevant national guidance
- 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 to treatment was obtained, in line with the [Department of Health's advice on consent](#) (2009).

9.2 Recommendations and research recommendations

39. When supplying and/or administering a medicine under a PGD, health professionals should follow local organisational policies and act within their code(s) of professional conduct and local governance arrangements (see recommendations 60 and 61).

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

- **have undertaken the necessary initial training and continuing professional development**
- **have been assessed as competent and authorised to practise by the [provider organisation](#) (see recommendation 36)**
- **have signed the appropriate documentation (see recommendation 36)**
- **are using a copy of the most recent and in date final signed version of the PGD (see recommendation 37)**
- **have read and understand the context and content of the PGD.**

41. When practising under a PGD, health professionals should:

- not [delegate](#) their responsibility
 - ensure that they can determine that the patient meets the inclusion criteria as set out in the PGD
 - ensure that they can determine that no exclusion criteria apply
 - 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, including maintenance of the 'cold chain'
 - follow-up arrangements
 - be able to advise the patient or their carer about the medicine(s), as appropriate.
42. When supplying a medicine(s), provide an [appropriately labelled pack](#). Health professionals (other than pharmacists or dispensing doctors) should not split packs.
43. Ensure that the patient receives a manufacturer's patient information leaflet with each medicine.
44. Identify whether patients supplied with a medicine(s) under a PGD are exempt from NHS prescription charges. The appropriate prescription charge(s) must be collected from patients who are not exempt, in line with [National Health Service \(Charges for Drugs and Appliances\) Amendment \(No. 2\) Regulations 2000](#).
45. 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 the patient met the criteria of the PGD
 - details of medicine, such as name, strength, dose, frequency, quantity, route and site (if by injection) of administration (record the batch number and expiry date for vaccines, blood-derived products and other medicines if recommended by relevant national guidance)
 - a statement that supply or administration is by using a PGD
 - name and signature (which may be an electronic signature) of the health professional supplying or administering the medicine
 - relevant information that was provided to the patient or their carer
 - whether patient consent to treatment was obtained, in line with the [Department of Health's advice on consent](#) (2009).

10 Reviewing and updating patient group directions

10.1 Evidence to recommendations

Table 7: Linking evidence to recommendations (LETR)

The Committee discussed that many organisations have a significant volume of existing PGDs in use within their services. The Committee recognised that the workload and resources needed to review and update a large volume of PGDs was significant.

The Committee agreed that organisations should establish and manage a work programme, to ensure that sufficient resources are available for reviewing, updating and reauthorising PGDs within the legal requirements. The Committee's view was that the review and updating should start at least 6 months before the PGD expires to allow sufficient time to complete the process.

Frequency of reviewing and updating a patient group direction

The [Health Service Circular \(HSC 2000/026\)](#) states that 'generally, a direction should be reviewed every two years'. However, the GDG was aware that this was not required by legislation. The Committee also found evidence of PGD use being monitored and evaluated locally, before reviewing and updating the PGD (see [section 12](#)). The Committee discussed the issue of the review period and agreed that in some circumstances, it may be appropriate to review and update the PGD less frequently than every 2 years. In other circumstances, a planned review period of less than 2 years may be necessary. The Committee also agreed that staggering review dates may help to support the work programme. The Committee recognised that PGDs must not be used beyond their expiry date, because any supply and/or administration of a medicine(s) would be without legal authorisation. The Committee concluded that the expiry date for a PGD should be considered and determined locally on a case-by-case basis with patient safety paramount. This should be a maximum of 3 years from the date the PGD was authorised.

Process for reviewing, updating and reauthorising a patient group direction

Evidence identified shows that PGDs are usually reviewed and updated by the lead author, supported by a [PGD working group](#) (see [section 7](#)). The process for reviewing and updating a PGD should include an appropriate literature search to identify new evidence. This then needs to be evaluated to assess its relevance and validity. However, the Committee agreed that the process for reviewing and updating should not only consider the clinical and pharmaceutical content of the PGD. The process should also include reviewing the delivery of the service and frequency of PGD use to assess whether the PGD remains the most appropriate option (see [section 5](#)).

The Committee determined that the process should also allow for an unscheduled review of a PGD earlier than the designated review date. This should include responding to:

- changes in legislation
- important new evidence or guidance that changes the PGD, such as new national guidance
- new information on drug safety
- changes in the [summary of product characteristics](#)
- changes to the local formulary.

Reauthorisation of an updated PGD should follow the same process as the original authorisation (see [section 8](#)). In addition, when the PGD is reauthorised, the expiry date and record of health professionals authorised to practise under the PGD should be updated and new documentation signed by the health professionals authorised to practise under the PGD (see [sections 8](#) and [9](#)). The Committee agreed that organisations also need to ensure

that an updated PGD is communicated and disseminated effectively to all relevant stakeholders (see [section 8](#)).

10.2 Recommendations and research recommendations

46. Establish and manage a structured work programme for reviewing, updating and reauthorising PGDs. Ensure that sufficient resources are available to deliver the work programme.
47. Ensure that a named lead author has responsibility for reviewing and updating the PGD, supported by a locally determined multidisciplinary [PGD working group](#). Include a doctor (or dentist), pharmacist and representative of any other professional group(s) using the PGD. Define their roles and responsibilities and consider their training and competency needs (see recommendation 22).
48. When reviewing the PGD, conduct an appropriate literature search to identify new evidence. Ensure that this evidence is evaluated to assess its relevance and validity.
49. 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, such as patients or their carers.
50. Determine the expiry date for an individual PGD on a case-by-case basis, with patient safety paramount. Ensure that this date does not exceed 3 years from the date the PGD was authorised.
51. Ensure that an updated PGD is reauthorised, in line with the [Human Medicines Regulations 2012](#) (see recommendations 30 to 34).
52. When a PGD is updated, ensure all relevant documentation is also updated, including the record and signatures of health professionals authorised to practise under the PGD (see recommendation 65).
53. Ensure that an updated PGD is communicated and disseminated effectively to all relevant stakeholders (see recommendation 35 and 37).
54. 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
 - 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.

11 Training and competency

11.1 Evidence to recommendations

Table 8: Linking evidence to recommendations (LETR)

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

- the [NHS Specialist Pharmacy Service \(SPS\) website PGD resources](#)
- the competency framework included within 'Patient Group Directions – a practical guide and framework of competencies for all professionals using patient group directions', published by the National Prescribing Centre^c (2009).

The Committee recognised that the [Health Service Circular \(HSC 2000/026\)](#) states that 'a senior person in each profession should be designated with the responsibility to ensure that only fully competent, qualified and trained professionals operate within directions'. The Committee found that the training of health professionals in using PGDs appeared to be an important consideration in some organisations, but not in all. It found some examples of locally developed training resources that health professionals needed to complete before being authorised to practise under the PGD (see [section 8](#)).

The Committee recognised the importance of continuous professional development, and in particular that health professionals supplying and/or administering medicines under a PGD are trained and assessed as fully competent to do so. The Committee agreed that PGDs are not suitable for health professionals who are undergoing relevant training, for example, for administering intramuscular injections.

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

- members of the [PGD approval group](#) (see [section 6](#))
- members of the PGD working group (see [section 7](#))
- people signing PGDs (see [section 8](#))
- people authorising named, registered health professionals to practise under the PGD (see [section 8](#)).

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

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

The Committee concluded that training and assessment of competency is essential to reduce variation and deliver safe and effective services in which PGDs are used. Organisations should establish a training programme that supports all people involved with PGDs. In the absence of a comprehensive suite of nationally produced educational materials, organisations may want to consider collaborating and sharing their existing educational materials to ensure a comprehensive approach.

Knowledge, skills and expertise

The Committee considered that any person involved with PGDs will need knowledge, skills and/or expertise in a number of specific areas that include:

^c The National Prescribing Centre became part of NICE in April 2011

- 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
- ability to use standard software packages and the internet to search for and resource information
- records management, including version control.

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

The Committee considered that additional specialised knowledge, skills and expertise are needed for people who are fulfilling specific roles in the process. The Committee agreed that the [local decision-making competency framework](#), produced by the National Prescribing Centre (2012), could be used to assess the membership of the PGD approval group and identify any gaps in competency.

The Committee agreed that the additional specialised knowledge, skills and expertise needed by individual people and groups. These are provided below:

People in a PGD working group^d

- evidence gathering and critical appraisal
- clinical and pharmaceutical knowledge, such as drug interactions, contraindications and adverse effects
- authoring clinical content
- medicines management systems, such as safe storage, packaging and labelling.

Doctor (or dentist) signing a PGD

- relevant specialist clinical and pharmaceutical knowledge, including national guidance and policy
- experience of working at a level of responsibility appropriate to the role
- experience of working in a local medicines decision-making group
- understanding of the clinical speciality or service in which the PGD is to be used.

Pharmacist signing a PGD

- relevant specialist clinical and pharmaceutical knowledge, including national guidance and policy
- experience of working at a level of responsibility appropriate to the role
- experience of working in a local medicines decision-making group
- understanding of the clinical speciality or service in which the PGD is to be used
- medicines management systems, such as safe storage, packaging and labelling.

Other people signing a PGD (representing any other professional group(s) using the PGD)

- experience of working at a level of responsibility appropriate to the role

^d Members of the group should together have the knowledge, skills and expertise needed to undertake all necessary activities.

- specialist practitioner in the clinical speciality or service in which the PGD is to be used
- experience of working in a local medicines decision-making group.

A person signing PGDs on behalf of the authorising body

- organisational responsibility for clinical governance
- experience of working in a local medicines decision-making group.

People authorising named, registered health professionals to practice under the PGD

- experience of working at a level of responsibility appropriate to the role in the relevant profession
- experience of working in the clinical speciality or service in which the PGD is to be used
- ability to incorporate relevant professional standards
- ability to incorporate appropriate training and development for the relevant profession.

People using PGDs

- clinical and pharmaceutical knowledge, such as drug interactions, contraindications and adverse effects
- experience of working in the clinical speciality or service in which the PGD is to be used
- medicines management systems, such as safe storage, packaging and labelling.

11.2 Recommendations and research recommendations

55. Identify the senior person in each profession who is responsible for ensuring that only fully competent, qualified and trained health professionals use PGDs.
56. Identify gaps in competency and establish a comprehensive and appropriate training programme for all people involved in considering the need for, developing, authorising, using and updating PGDs.
57. Ensure that adequate educational materials are available to enable individual people and [organisations](#) to deliver safe and effective services in which PGDs are used.
58. Consider collaborating with other organisations and sharing existing educational materials to ensure a comprehensive approach.
59. Ensure that training and re-training of health professionals using PGDs incorporates a post-training assessment of competency.

12 Organisational governance

12.1 Evidence to recommendations

Table 9: Linking evidence to recommendations (LETR)

The Committee was aware that models for delivering healthcare in the NHS are currently changing. This good practice guidance provides an opportunity for [commissioning](#) and [provider](#) organisations to review local policies and governance arrangements to support the safe and effective use of PGDs. The Committee agreed that commissioners should ensure that arrangements are consistent, regardless of whether the provider is an NHS or independent organisation.

During its deliberations, the Committee recognised the importance of the commissioning and provider organisation(s) working closely from an early stage to incorporate the necessary governance arrangements covering each step of the PGD process as outlined in [section 4.2](#). These local governance arrangements should establish clear lines of accountability and responsibility between the commissioning and provider organisation(s). It is likely these will need to be considered for each PGD on a case-by-case basis. The responsibilities and reporting arrangements should be stated in a [service level agreement](#) or [contract specification](#). [Key performance indicators \(KPIs\)](#) (these are used to help define and measure progress towards organisational goals) or quality metrics may be included. Arrangements should ensure that providers comply with the fundamental standards set by the [Care Quality Commission](#).

The Committee noted that not all organisations had a documented PGD policy and associated procedures that outlined each stage of the process across their organisation. The Committee agreed that the PGD policy should be publicly available, and may be part of a wider organisational medicines policy.

The Committee agreed that, to ensure local processes and governance arrangements are followed, a designated person in each organisation should have overall organisational responsibility. In an [authorising body](#), this is likely to be the person authorising PGDs on behalf of the organisation, such as the clinical governance or patient safety lead (see [section 8](#)).

Patient safety incidents

The Committee agreed that governance arrangements should include the process for reporting [patient safety incidents](#) relating to PGD use, such as medication errors, near misses and suspected adverse events. These arrangements should be included in existing local processes, but not replace national patient safety reporting systems, including the [yellow card scheme](#).

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

Monitoring and evaluation

In its review of the evidence, the Committee found that monitoring and evaluation of PGD use within the service helps to:

- ensure that PGDs are used appropriately and deliver safe and effective care
- confirm that the PGDs are meeting both patient and service needs
- facilitate reflection on current practice.
- The Committee was aware of [resources](#) available on the NHS Specialist Pharmacy Service (SPS) website
- to support organisations with monitoring and evaluation.

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

Organisational records

The Committee acknowledged the importance of maintaining, storing and archiving appropriate organisational records.

The [Health Service Circular \(HSC 2000/026\)](#) states that ‘there must be a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and out-goings on a patient by patient basis’ (see [section 9](#)). All records and documentation relating to PGDs should comply with information governance arrangements outlined in the [Department of Health’s Code of practice on records management](#) (2006), for example, data protection, confidentiality and duration records should be securely stored.

The Committee agreed that it was good practice to maintain and review the following records:

- patient safety incidents relating to PGD use, such as medication errors, near misses and suspected adverse events
- terms of reference and minutes or notes of the [PGD approval group](#) (see [section 7](#))
- a list of all organisational PGDs that are in use, including their review date and expiry date (see [section 10](#))
- master authorised copies of PGDs (see [section 8](#))
- expired versions of PGDs
- members of the [PGD working group](#) (see [section 7](#))
- signatures of people signing a PGD (see [section 8](#))
- a list of named, registered health professionals authorised to practise under each PGD used within the service (see [section 8](#))
- training records (see [section 11](#))
- results of monitoring and evaluation.

12.2 Recommendations and research recommendations

- 60. For each PGD, the [commissioning](#) and [provider organisation\(s\)](#) should collaborate to firmly establish local governance arrangements with clear lines of responsibility and accountability.**
- 61. Develop or review the organisational PGD policy and associated procedures to ensure that robust and transparent processes are documented. Ensure that the PGD policy is publicly available.**
- 62. Ensure that a designated person has overall organisational responsibility for PGDs.**
- 63. Ensure that [patient safety incidents](#) relating to PGD use are reported, collated and reviewed by the appropriate [organisations](#) in a planned programme, in line with national patient safety reporting systems.**
- 64. Agree and undertake a planned programme of monitoring and evaluation of PGD use within the service.**

- 65. Ensure that 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 should include:**
- patient safety incidents, such as medication errors, near misses and suspected adverse events
 - terms of reference and minutes or notes of the [PGD approval group](#)
 - a list of all PGDs in use within the organisation, including their review date and expiry date
 - master authorised copies of PGDs
 - expired versions of PGDs
 - members of the [PGD working group](#)
 - signatures of people signing a PGD
 - a list of named, registered health professionals authorised to practise under each PGD used within the service
 - training records
 - results of monitoring and evaluation.

13 References

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

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

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

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

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

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

National Patient Group Directions website (now [Specialist Pharmacy Services website](#))

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

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

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

Standards for medicines management (2007) Nursing and Midwifery Council

Patient Group Directions: guidance and information for nurses (2006) Royal College of Nursing

14 Glossary

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

Administer

To give a medicine by either:

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

Appropriately labelled pack

In most cases, the pack to be issued under a PGD will need to be labelled to reflect the dose exactly as authorised in the PGD, as if it were being dispensed against a prescription. Separate requirements exist for prescription-only medicines (POMs) and for Pharmacy (P) and General Sales List (GSL) medicines. In practice, medicines supplied for use under a PGD are often in packs that are pre-labelled by a licensed manufacturing unit. These labels include all the standard labelling requirements, leaving a space on the pack for the patient's name, date of dispensing and address of the supplying service to be added at the time of supply. This is sometimes known as over-labelling.

Black triangle medicine

Black triangle medicines are licensed medicines that are intensively monitored and subject to special reporting arrangements for adverse events.

Contract specification

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

Delegation

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

Dispense

To label from stock and supply a clinically appropriate medicine to a patient, carer or client, usually against a written prescription, for self-administration or administration by another professional, and to advise on safe and effective use.

General Sales List (GSL) medicine

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

Healthcare-associated infections (HCAI)

HCAI can develop either as a direct result of healthcare interventions, such as medical or surgical treatment, or from being in contact with a healthcare setting. The term HCAI covers a wide range of infections, including those caused by methicillin-resistant *Staphylococcus aureus* (MRSA), methicillin-sensitive *Staphylococcus aureus* (MSSA), *Clostridium difficile* (*C. difficile*) and *Escherichia coli* (*E. coli*).

Independent prescribing

Independent prescribers (doctors, dentists and non-medical independent prescribers) take responsibility for the clinical assessment of the patient, establishing a diagnosis, the clinical management needed and prescribing. Also see 'Supplementary prescribing'.

Inherited PGDs

Licensed medicine

A medicine that has a UK marketing authorisation.

Marketing authorisation

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

Non-medical prescribing

Non-medical prescribing includes:

- independent prescribing by specially trained nurses, pharmacists, optometrists, physiotherapists, podiatrists and radiographers working within their clinical competence.
- supplementary prescribing by specially trained nurses, midwives, optometrists, pharmacists, physiotherapists, podiatrists and radiographers.

Off-label use

Using a UK licensed medicine outside the terms of its marketing authorisation, such as outside defined indications, doses or routes of administration. For example, when amitriptyline is used for neuropathic pain.

Patient safety incident

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

Patient specific direction (PSD)

Written instructions, signed by a doctor, dentist or non-medical prescriber for a medicine to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis.

Pharmacy (P) medicine

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

Prescribe

To authorise in writing the supply and administration of a medicine or other healthcare treatment for a named individual patient.

Prescription-only medicine (POM)

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

Public-funded service

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

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

Service level agreement (SLA)

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

Social enterprise

A social enterprise is a business with primarily social objectives whose surpluses are principally reinvested for that purpose in the business or in the community, rather than being driven by the need to maximise profit for shareholders and owners.

Special manufactured medicines

Special order unlicensed medicines, or 'specials', that are made to meet the needs of an individual patient, when an appropriate licensed formulation is not available.

Supplementary prescribing

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

Supply

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

Unlicensed medicine

A medicine that does not have a UK marketing authorisation.