1. SCOPE

This document:

- Does not replace or supersede existing national guidance but provides links to national guidance and other resources such as audit tools and PGD policies.

- Is intended to be read as a complete document to help provide the full context in practice.

- Outlines the arrangements and procedures that local authorities are advised to put in place for considering the need for, development of, authorisation of, use and updating for Patient Group Directions (PGDs);

- Describes arrangements to support the use of PGDs in services commissioned by local authorities and identifies models of good practice for commissioners for reference.

- Does not cover arrangements for the implementation of PGDs such as training and competency assessments.

2. Background

[**NICE PGD Medicines Practice Guidelines (MPG2) 2013**](#) refers to Health Service Circular (HSC 2000/026) which states that 'the majority of clinical care should be provided on an individual, patient-specific basis' i.e. prescribing remains the preferred option for the majority of care.

PGDs are one of a number of other options for supply and/or administration of medicines and their use should be reserved for situations in which this offers an advantage for patient care, without compromising safety.

Patient Group Directions (PGDs) are defined as 'Written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment'.

They provide a legal framework that allows authorised registered health professionals to supply and/or administer a specified medicine(s) to a pre-defined group of patients, without them having to see a prescriber.

PGDs can be particularly useful for providing access to medicines in services delivered by nurses or pharmacists such as smoking cessation, sexual health, and substance misuse. However, before developing or reviewing or authorising a PGD, local authorities should consider carefully whether a PGD is the most appropriate option for delivering the service in question.
3. PGD legislation and related national guidelines

The development and authorisation of PGDs is subject to specific statutory and governance requirements.

The current legislation for PGDs is included in The Human Medicines Regulations 2012 and subsequent amendments.

Local authorities that commission services using PGDs should refer to the Department of Health Sexual Health: Clinical Governance in October 2013 paper which outlines key principles to assist service commissioners and providers to operate clinical governance systems in sexual health services.

NICE PGD Medicines Practice Guidelines (MPG2) 2013 provide good practice recommendations and covers governance arrangements with the aim of ensuring patients receive safe and appropriate care and timely access to medicines, in line with legislation. The NICE PGD Pathway is useful to use as a step-wise approach.

The national PGD website provides resources to support organisations considering the need for a PGD such as “To PGD or not To PGD” and other tools.

Legislation states that the PGD must be signed by a doctor (or, if appropriate, a dentist) and a pharmacist, who have been involved in the development of the PGD and are responsible for ensuring that the clinical and pharmaceutical content is safe and accurate, and supported by the best available evidence.

NICE PGD Medicines Practice Guidelines (MPG2) 2013 adds that [this should be undertaken by senior professionals with full consideration of the clinical service in which the PGD is to be used] . It also states that the PGD 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. Their role is to provide specialist professional advice and support including provision of information on service delivery within their clinical area.

For the purposes of this paper, we will call the doctor, pharmacist and the representative of the professional group “clinical signatories” who are required for clinical authorisation. See Section 5.2.

Additionally the PGD must be authorised by the relevant authorising body as set out in the legislation. In this paper the authorising body is the local authority unless otherwise mentioned.

Since April 2013, local authorities have been listed in PGD legislation as an authorising body for PGDs within the services they commission.

Local authorities that commission services using PGDs need to take action with reference to NICE PGD Medicines Practice Guidelines (MPG2) 2013.
NICE PGD Medicines Practice Guidelines (MPG2) 2013 provide good practice recommendations for the systems and processes used when commissioners and providers of NHS and 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.

4. Arrangements and procedures for considering the need for, development of, authorisation of, use and updating for Patient Group Directions (PGDs).

Local arrangements and procedures can vary depending on many factors but these should meet the requirements of NICE PGD Medicines Practice Guidelines (MPG2) 2013.

NICE PGD Medicines Practice Guidelines (MPG2) 2013 states:

[GDG 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 3.8). A number of scenarios may exist for developing and authorising PGDs.

When a recommendation is aimed specifically at an individual person or organisation, this is clearly identifiable. However, in many cases, the GDG 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 GDG agreed that arrangements will vary depending on local organisational structures, how services are commissioned and provided, and what resources are available.]

5. What are the implications for sexual health commissioners in Local Authorities in London?

5.1 PGD Development

Either the commissioner or provider organisation could have responsibility for developing PGDs. This is for commissioners and providers to consider and determine locally.

London Contraception and Sexual Health PGD Group (LSH) develop PGD templates following NICE PGD Medicines Practice Guidelines (MPG2) 2013 processes for PGD development. The templates still require clinical and organisational authorisation. However, adopting these templates ensures that standards of care are consistent across their locality and across London and also is an efficient use of resource, preventing duplication of effort.

For these reasons, it is suggested that the clinical signatories of the PGDs should not change clinical content. If this is deemed necessary, then it is advised that the clinician contacts the London SH PGD Group Chair or Advisor to discuss any clinical reasoning for the proposed change.

For more information about the templates and related processes, follow this link.
There is no “organisational structure” to enable the London SH PGD Group or individuals to “legally sign off” the clinical content of the templates.

It has been agreed with the London Sexual Health Strategic Commissioning Leads to scope the possibility of a “one off” clinical signatory authorisation for London during 2015-2016.

In the meantime, local authorities must make their own arrangements for both the clinical and organisational authorisation of the PGDs.

5.2 Clinical authorisation of PGDs

Where local authorities do not have sufficient resources and/or expertise available to develop and authorise PGDs, they can consider a variety of routes for clinical authorisation of PGDs. (See Section 3)

Some independent healthcare providers may have the resources and capacity to develop or authorise the clinical content of the PGD templates but do not have the legal authority for organisational authorisation.

For others, such as community pharmacy or general practice, and for practical and legal reasons, it is necessary for the commissioning organisation to lead on both the development and authorisation (clinical and organisational) of the PGDs.

Where commissioners are unable to identify local expertise to support the development and/or update of PGDs and associated processes, the local authority could contact pharmacist advisers at the CCG or CSU who may be able to facilitate finding the appropriate expertise through local Pharmacy and/or medical networks. See 5.4 below.

5.3 Organisational authorisation of PGDs

Commissioners should have identified if any of the services they commission are using PGDs.

If the service is provided by an NHS Trust, the NHS Trust has legal authority to develop and authorise PGDs used in the delivery of their services.

Where the local authority has identified that it is required to authorise PGDs for providers, the local authority will need to determine the most appropriate process for developing and authorising PGDs for use in their commissioned services.

If the service is provided by an independent healthcare provider such as Brook, Terrence Higgins Trust or primary care contractors such as community pharmacists, then the local authority must authorise PGDs for these provider organisations.

This arrangement may require clinical as well as organisational authorisation where there is no capacity or it is impractical to do so e.g. EHC service commissioned from several community pharmacy contractors.
Action should be supported by an appropriate medicines governance structure and processes that meet legislative requirements and comply with [NICE PGD Medicines Practice Guidelines (MPG2) 2013](https://www.nice.org.uk/). It is a local decision that determines the most appropriate arrangements for PGD management, and for the local authority to devise an action plan to deliver this.

Legislation states that organisational authorisation of PGDs by a local authority must be carried out on behalf of the Chief Executive or Director of Public Health of the local authority.

This may be a nominated clinical governance lead. A clinical governance lead responsible for organisational authorisation (“signing off”) of a PGD is authorising that a PGD is fit for purpose i.e. it has been developed according to the correct organisational procedures and that those involved in the development and clinical authorisation of the direction are competent to do so.

The “clinical governance lead” may not be employed with this particular job title but their role may incorporate this responsibility. The organisational structure would need to determine which individual would have the authority and responsibility to be the signatory in order to state that PGDs are fit for purpose. For example, this may delegated to an individual whose role incorporates clinical governance responsibilities.

See PGD Website FAQ which covers [Responsibilities of signatories](https://www.nice.org.uk/). 

### 5.4. Can a local authority delegate authorisation of PGDs to a CCG using a "Section 75" partnership agreement?

No.

The Medicines and Healthcare Products Regulatory Agency (MHRA) has sought legal advice and has confirmed that local authorities cannot delegate responsibility for organisational authorisation of PGDs to Clinical Commissioning Groups (CCGs) under a Section 75 agreement.

Please refer to the [PGD website Frequently Asked Question](https://www.nice.org.uk/) (FAQ) where this is covered in more detail.

### 6. Clinical governance responsibilities

See [NICE PGD Pathway](https://www.nice.org.uk/) Organisational Governance section.

Independent healthcare providers registered with the Care Quality Commission and commissioned to provide sexual health services under an arrangement with an NHS body or a local authority must have their PGDs authorised by the relevant commissioning organisation. They must also comply with all the legal requirements of a PGD and – as is the case with all providers – they remain responsible for ensuring that health professionals are competent and authorised to work to the PGD and that appropriate governance systems and processes are in place.
Whatever arrangements the local authority decides to put in place for the development and authorisation of PGDs, they will need to ensure there are robust local governance arrangements in place.

To ensure continuation of safe and effective care, it is advised that a nominated group or committee led by the nominated clinical governance lead in the local authority will:

- ensure that PGDs are developed and authorised in accordance with the good practice recommendations in NICE PGD Medicines Practice Guidelines (MPG2) 2013. These guidelines and associated resources apply to local authorities.
- agree timeframes for all planned outputs ensure the relevant systems and processes are in place to comply with the legal framework and any associated national guidance.
- have processes in place to be assured that providers have suitable clinical governance arrangements including medicines management systems and procedures, training, assessment of competencies and audit.
- have processes in place to be assured that there is a robust clinical governance process, that the service provides appropriate access to medicines for its population and that there is consistency in clinical care.
- be responsible for communicating the arrangements for medicines management in such contracts to all key personnel/services
- keep a database of all Provider services where its PGDs are in use.

7. Extension of expiry dates for PGDs

Local authorities could consider extending the expiry date of a PGD for a short period. This is not without risk particularly where service delivery models and clinical guidelines may also have changed.

There should be agreed local processes for extension of expiry dates and review of existing PGDs. This is an organisational not an individual responsibility.

For more information, see the FAQ section on the PGD website “Is extension of an expiry date of a PGD allowed without review and re-authorisation of the PGD?”

The medicines decision-making committee of the CCG such as the Medicines Management Committee cannot extend the expiry dates of PGDs for services commissioned by the LA. The committee may provide clinical opinion or guidance to the LA as to whether this is safe or appropriate. Please refer to the PGD website for further information.
8. Useful resources and information

To discuss any local issues, contact the London Sexual Health Strategic Commissioning Leads in the first instance.

8.1 Audit tools

The baseline assessment tool developed by NICE can be used by local authorities to identify whether their processes are in line with practice recommended in NICE MPG2 PGDs and to help them plan activity that will help them meet the recommendations. It should also be used by provider organisations using PGDs. Link to Examples of PGD audit tools

8.2 Competency tools

PGDs should only be developed, updated and authorised by individuals with the competence to fulfil these roles. NICE has published competency frameworks for those individuals involved in developing, updating, authorising and using PGDs.

Competency framework for people developing and/or reviewing and updating patient group directions

Competency framework for people authorising patient group directions

Competency framework for health professionals using patient group directions

8.3 PGD Website FAQs

8.4 Examples of PGD policies/processes

Cheshire and Merseyside Public Health Collaborative Service

London Borough of Richmond Local Authority PGD Policy and Service Level Agreement.

London Borough of Bromley Public Health PGD Policy

Northwest Manchester CSU PGD Policy (working with 7 local authorities)

8.5 Examples of PGD templates including London Sexual Health PGD Templates and PGD Policies.

The national PGD Website has a number of quality assured examples of local authority PGD arrangements. These include:

London Sexual Health Programme PGD Templates

Community Pharmacy West Yorkshire

Cheshire and Merseyside Public Health Collaborative Service (CHAMPS)

NW Manchester Commissioning Support Unit
8.5. Example of London Borough PGD arrangements.

With reference to the use of London SH PGD templates, one local Borough has developed the following authorisation arrangements and systems:

Medical Signatory – member of the Public Health senior team is medically qualified and a Consultant in Public Health.

Pharmacist Signatory - initially commissioned a local pharmacist to work on training and some PGD development, along with some other Public Health commissioned work such as Pharmacy Needs Assessment. Current process involves Local Pharmaceutical Committee (LPC) Chair to sign off the PGDs and support training. If he is unavailable, he deputises this role to the LPC Deputy.

Clinical Contraception / Sexual Health Lead - current programme lead who has Contraception and SH nursing background.

Board Approval - Clinical Governance Authorising Group (CGAG) All other signatories must be present on the document before the PGD can be submitted for Board Approval. The PGD requiring approval is circulated to the CGAG board 10 days before their scheduled meeting and on the agenda for discussion. If any queries arise from the discussion at this meeting they may be resolved externally and possible sign off approval or authorisation by Director of Public Health (DPH) outside this time frame.

Local Authority Signatory - Director of Public Health (DPH) on behalf of the LA and as Chair of CGAG

Additional Support
- Informal Microbiologist residing within local NHS Trust.
- CCG Lead pharmacist (Head of Medicines Management) is member of LA PH CGAG Board.

PGD Policy for Development, Approval and Implementation of Patient Group Directions’ is in final stages of development and will be shared in due course. It consists of 3 parts:
- Part 1 - General - general guidance covering aims, background, when and when not to PGD etc.
- Part 2 - PGDs developed by Public Health [PH] to be used by services commissioned by PH from independent providers [i.e. community pharmacists]
- Part 3 - Procedure for authorising PGDs developed by an external organisation for PH commissioned services.

Communication to community pharmacy providers:
- Existing providers are informed and changes made clear by letter and email. Two copies of the new PGD documents are sent by post, requesting a copy is signed and returned by each community pharmacist to the programme lead for LA Authorising signature. A fully signed copy is returned to the pharmacist. The original is kept on file.
- New Providers must receive training in a combination of CPPE completions, self declaration of competencies, and importantly, local input from programme lead.