



NHS England North - Yorkshire and the Humber Region
Protocol for the Development, Authorisation and Use of Patient Group
Directions for the National Immunisation Programmes

1. Introduction

The preferred way for patients to receive the medicines they need is for a prescriber to provide care for an individual patient on a one-to-one basis.

PGDs provide a legal framework that allows some 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. However, 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. Whilst they allow the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment, the use of PGDs should not be interpreted as indicating that the patient should not be identified and assessed prior to administering the medicine.

This guidance applies to NHS England North (Yorkshire and the Humber). It is aimed at developers of PGDs, commissioners and providers of NHS commissioned services in relation to the development, review, authorisation and use of PGDs to support delivery of the national immunisation programmes in a variety of settings. This process applies to PGDs developed nationally and locally but does not extend to non-NHS commissioned healthcare services or travel vaccines that are not supplied free on the NHS as these do not fall under the remit of the PHE/NHS England. Travel vaccines to be included are Polio containing vaccines, Typhoid containing vaccines, Cholera vaccines and Hepatitis A containing vaccines as these are provided free of charge on the NHS.

Whilst PGDs may be developed for use across multiple organisations, each PGD requires authorisation prior to use by the person with responsibility for governance and/or patient safety within the authorising organisation i.e. the commissioner of the NHS service to which the PGD applies. The PGD should then be formally adopted and signed by the governance Lead within each provider organisation.

PGDs are permitted for use only by registered health professionals (see enclosed link for full list <http://www.nice.org.uk/guidance/mpg2>)

2. The purpose of a PGD is 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.

3. PGD Development Group

The development and review of PGDs will be overseen by the PGD Steering Group, with individual PGDs being the responsibility of a PGD Development Team, consisting of a Pharmacist, Medical Practitioner and Nurse. A lead author will be identified from within the Medicines Management Teams/CSU, who will be supported by nursing and medical input from NHS England North (Yorkshire and the Humber) Screening and Immunisation Team and PHE Centre (Yorkshire and the Humber) respectively. Prior to authorisation the PGD will be circulated to the PGD Steering Group for consultation. The PGD development group will ensure that the content of PGDs is in line with the requirements outlined in the Medicine Practice Guideline (appendix 1)

PGDs may be developed by the PHE National Immunisation Team. These will be circulated as templates to allow local additions, although these will not permit changes to the body of the PGD. These templates are not legal documents until they have been authorised following the process identified above.

The use of unlicensed medicines **is not** permitted under PGDs, however where a recommendation is made by Joint Committee for Vaccination and Immunisation, 'off label' use will be permitted under the justification of best clinical practice. Where this is the case, this will be clearly identified on the PGD.

4. Reviewing PGDs:

There will be a structured work programme for the review of existing PGDs, coordinated by the Screening and Immunisation Manager. In the absence of new clinical evidence or national guidance PGDs will generally be reviewed every two years (this will not exceed three years). Reviews will take account of new clinical evidence, the current chapter of the Green Book, the Manufacturers Summary of Product Characteristic (SPC) sheet, any change to legislation, changes to local formulary, new information on drug safety, changes to vaccine name etc.

5. Authorisation of Patient Group Directions:

Legislation requires that prior to authorisation a PGD must be signed by a doctor (or dentist) and a pharmacist. The responsibility of the doctor/dentist and pharmacist signatories is to establish that the clinical and pharmaceutical content is accurate and supported by the best available evidence, this is a joint accountability. In order to fulfil this requirement locally developed PGDs will be signed by the medical (doctor) and pharmacist representative of the development group prior to seeking authorisation from the Medical Director and/or Nurse Director (patient safety lead) responsible for NHS England North (Yorkshire and the Humber).

PGDs produced by the National Immunisation Team, will be reviewed by and signed off by nominated members of the PGD Steering Group prior to authorisation by the Medical Director for NHS England North (Yorkshire and the Humber).

Within the NHS in England organisations categorised as authorising bodies are:

- CCGs
- Local Authorities

- NHS trusts or NHS foundation trusts
- Special health authorities
- The NHS Commissioning Board (now NHS England).

It is recommended that the persons authorising the PGD have not been involved in the development of or will be practising under the PGD

Independent Hospitals and Medical Agencies e.g. Social Enterprises cannot legally authorise PGDs to provide NHS Commissioned Services. Whilst they may have the expertise and resource to develop them, they do not have legal authority to authorise them, this obligation must therefore be filled by the Commissioning Organisation.

Process for Authorisation:

- Final versions of PGDs to be submitted to NHS England North (Yorkshire and the Humber) Medical/Nurse Directors
- PGDs will be authorised by the Medical Director/ Nurse Director using electronic signatures.
- Following authorisation the Personal Assistant to the Chief Nurse (Director of Nursing) will forward the signed version of the PGD to the Screening and Immunisation Manager for conversion to PDF and distribution to all NHS England - North (Yorkshire and the Humber) Screening and Immunisation Teams.
- Screening and Immunisation Teams to ensure distribution within their geographical area as per local agreement.
- The Screening and Immunisation Manager will forward the PDF document to NHS England IT team to upload on to the NHS England North (Yorkshire and the Humber) web page.
- Screening and Immunisation Teams, CCGs and CSUs to ensure links publicised accordingly.

Whilst it is recognised that distribution via email is through blind copy, the body of the email will identify who the information has been sent to.

Adoption for Use by Provider Organisations

In order to demonstrate that the provider has accepted their responsibility (e.g. training and competency assessment and monitoring use of PGDs), it is recommended within the NICE Medicines Practice Guidelines, that each PGD be formally adopted for use and co-signed by the individual provider organisation. Signatories should be the designated clinical governance lead/lead practitioner within that individual organisation, GP practice, pharmacy etc

Health professionals who will be using the PGD must be named and individually authorised by a nominated senior person on behalf of their employing organisation before practising under it.

The PGD must be distributed to and signed by each member of staff intending to work under/use the PGD – this should only be after the above two stages have been completed.

Responsibility of each Provider Organisation:

Each provider organisation must:

- Identify a senior, responsible person from within the service to authorise named, registered health professionals to practise under the PGD (see appendix 2)
- Ensure that authorised health professionals have signed the appropriate documentation
- Professionals are responsible and accountable for their own decisions and actions and must act within their appropriate code of professional conduct.
- Ensure timely and appropriate distribution within their organisation.
- Ensure that patient safety incidents relating to PGD use/Vaccine Related Incidents are reported to the local Screening and Immunisation Team based within NHS England. Incidents should be collated, and reviewed by the provider organisation in line with national reporting systems; ensuring significant event analysis and reviews are held where necessary.
- Undertake a planned programme of monitoring and evaluation of PGD used within their service. Evidence may be requested by the Commissioner as part of performance or contract review processes.
- 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.
- Ensure that all medicines administered under a PGD are appropriately READ coded in the patients clinical record. These are for:
 - SystmOne – XaQA7
 - Emis – 8BMN

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. Independent prescribers are not required to work under PGDs.

Where PGDs are not available, Patient Specific Directions (PSDs) should be used. These are written instructions, signed by a doctor, dentist, or nonmedical 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.

References

NICE, Medicines Practice Guidance – Patient Group Directions. 2nd August 2013 (updated February 2014)
<http://www.nice.org.uk/guidance/mpg2>

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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

Appendix 2: Knowledge, skills and/or expertise needed by people in specific roles

Role	Knowledge, Skills, Expertise
People in a PGD working group ^[a]	<ul style="list-style-type: none"> • 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 • Authorisation from their employing body.
Doctor (or dentist) signing a PGD	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • Experience of working at a level of responsibility appropriate to the role • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 • Documented authorisation, from the organisation using the PGD; approving the individual to work under the PGD.