

Patient Group Directions and Patient Specific Directions in General Practice

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There have been a number of regulatory and organisational changes within the NHS since the General Practitioners Committee (GPC) last produced guidelines on Patient Group Directions (PGDs) and Patient Specific Directions (PSDs) in 2010. In addition, NICE Medicines Practice Guideline 2 (MPG2)¹ was published in 2013 and as a consequence aspects of the original GPC advice have been updated, although many of the general principles and legislative requirements of PGDs remain the same.

Note that this guidance is for England only, although there are links to guidance in Scotland and Wales at the end of the document.

[The Human Medicines Regulations 2012](#) do not permit nurses, or other registered health care professionals (HCPs), who are not qualified prescribers to administer or supply prescription only medicines (POMs) unless one of three types of instruction is in place:

1. a signed prescription
2. a Patient Specific Direction (PSD)
3. a Patient Group Direction (PGD).

There are some specific exemptions from medicines legislation which may apply in limited circumstances e.g. administration of certain parenteral medicines such as adrenaline that can be administered in an emergency without the directions of a prescriber².

If non-prescribing health care professionals administer a medicine on the instruction of a GP, the GP must be able to show that the HCP has authority for that administration via one of the above methods.

To summarise:

- PGDs should be used only where appropriate, suitable and legal. To check use the flow chart "to PGD or not to PGD"³
- PGDs can be written by anyone involved with their use but the group should include a doctor/ dentist and a pharmacist who will sign it off
- PGDs can only be approved by certain bodies, in the cases relevant to general practice these are Clinical Commissioning Groups (CCGs), Local Authorities or NHS England

¹ www.nice.org.uk/guidance/MPG2

² www.legislation.gov.uk/ukxi/2012/1916/schedule/17/made

³ www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/PGD-Legislation-Guidance/PGD-Website-Tools/To-PGD-or-not-to-PGD-that-is-the-question/

- PGDs can only be used by certain registered health professionals listed in legislation⁴– this excludes Health Care Assistants
- there are certain categories of medicines for which a PGD should only be used with caution for example antibiotics, off license drugs, controlled drugs, or those subject to black triangles.

Patient Specific Directions (PSDs)

In general, most of the occasions where a non-prescribing health care professional supplies or administers a POM they do so under the terms of a PSD.

A Patient Specific Direction is an instruction from a doctor, dentist, or non-medical prescriber for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis.

There is no set protocol for PSDs written into the Legislation. As long as the prescriber (doctor or other registered health professional who is a qualified independent or supplementary prescriber) has considered the individual patient and has, as a consequence, given an instruction to supply or administer a drug to that patient the PSD is sound. There is no requirement for there to be a contractual relationship between the prescriber and the person carrying out the administration.

A PSD may be verbal or written but must be made after considering that individual patient and must constitute a clear instruction to the practice nurse or other competently trained health care professional to supply or administer the drug.

PSDs can be an electronic instruction, provided that it can be linked uniquely to the patient and the prescriber and is under his/her sole control. The PSD could also be a signed list of patients, such as in a flu or travel clinic. There is no requirement for the instruction to be defined as a PSD in the notes.

Some of the documents linked to in this guidance state that PSDs need to be in a written form, but this is not a requirement of the regulations. Health professionals need to be mindful of the requirements to maintain accurate patient records and the need to ensure that communications between them are understood. Where a verbal PSD is used it would be good practice to record the form of the direction alongside the accurate clinical record of the action(s) subsequently carried out.

⁴ www.legislation.gov.uk/ukxi/2012/1916/schedule/16/part/4/made

The NHS Patient Group Directions website contains set of FAQs about PSDs⁵.

Patient Group Directions (PGDs)

A Patient Group Direction is a written instruction for the supply and/or administration of medicines by named health care professionals to groups of patients who meet the criteria specified in the PGD.

PGDs, can be used in *“limited situations in which this offers an advantage for patient care, without compromising patient safety, and where there are clear governance arrangements and accountability”*⁶.

PGDs were introduced as a facilitative measure to allow some registered health care professionals to take a decision to supply or administer a POM to a patient with an identified clinical condition without the patient needing to see a prescriber. This can be useful in services where assessment and treatment follows a clearly predictable pattern (e.g. immunisation, family planning) or where a practice nurse has the experience and knowledge to make decisions on appropriate treatment (e.g. travel clinics). Because they are, in effect, giving someone without the legal ability to prescribe the right to supply or administer prescription only medication, they are instruments that should be subject to monitoring and checks.

Nurses using PGDs must have been assessed as fully trained and competent to use them and must comply with the standards set by their professional regulatory body, the Nursing and Midwifery Council’s *Standards for Medicine Management*.

For further information about using PGDs, see section 2.5 NICE MPG2 PGDs.

Particulars to be included in a Patient Group Direction

- a) The period during which the Direction shall have effect.
- b) The description or class of prescription only medicine (POM) to which the Direction relates.
- c) Whether there are any restrictions on the quantity of medicine which may be supplied on any one occasion, and, if so, what restrictions.
- d) The clinical situations which POMs of that description or class may be used to treat.
- e) The clinical criteria under which a person shall be eligible for treatment.
- f) Whether any class of person is excluded from treatment under the Direction and, if so, what class of person.

⁵ www.medicinesresources.nhs.uk/en/Communities/NHS/SPS-E-and-SE-England/Meds-use-and-safety/Leadership-workforce/Non-med-presc/Patient-Specific-Directions---QA/

⁶ Para 2.2.1 of NICE PGD guidance: www.nice.org.uk/guidance/mpg2/chapter/2-recommendations

- g) Whether there are circumstances in which further advice should be sought from a doctor or dentist and, if so, what circumstances.
- h) The pharmaceutical form or forms in which prescription only medicines of that description or class are to be administered.
- i) The strength, or maximum strength, at which prescription only medicines of that description or class are to be administered.
- j) The applicable dosage or maximum dosage.
- k) The route of administration.
- l) The frequency of administration.
- m) Any minimum or maximum period of administration applicable to prescription only medicines of that description or class.
- n) Whether there are any relevant warnings to note, and, if so, what warnings.
- o) Whether there is any follow up action to be taken in any circumstances, and, if so, what action and in what circumstances.
- p) Arrangements for referral for medical advice.
- q) Details of the records to be kept of the supply, or the administration, of medicines under the Direction.

Information on what should be included in a PGD is also set out in section 1.6 NICE MPG2 PGDs.

Questions and Answers

1. Can nurses who are not qualified prescribers administer or supply a prescription only medicine?

Yes. A GP can instruct a named practice nurse to supply or administer medicines on his or her behalf. However, medicines may only be administered by a practice nurse if one of three types of instruction is in place:

- a signed prescription
- a Patient Specific Direction (PSD)
- a Patient Group Direction (PGD).

[The Human Medicines Regulations 2012](#) do not permit nurses who are not prescribers to administer or supply POMs without a PSD or PGD or certain medicines exemptions in place or the item having been previously prescribed by a practitioner.

2. Can a nurse independent prescriber administer a POM without a PSD or PGD in place?

Yes. Nurse independent prescribers do not require a PSD or PGD in order to administer a POM. [Under the Human Medicines Regulations 2012](#) a nurse independent prescriber is able

to supply or administer any licensed medicine for any medical condition within their competence, including some controlled drugs for specified medical conditions.

3. When can PGDs be used in general practice?

In some circumstances, where assessment and treatment follows a clearly predictable pattern (for example where nurses are administering travel or childhood vaccinations to large groups of patients) practices may find it beneficial to have an agreed PGD in place so a GP does not have to give a specific instruction for each individual patient. A PGD enables a nurse to supply and/or administer prescription-only medicines to patients using his/her own assessment of patient need, in accordance with the criteria set out in the Human Medicines Regulations 2012 Schedule 16, Part 1⁷. The PGD must include this information.

A selection of example PGDs including those for vaccinations are available on the NHS PGD website⁸.

4. What role do LMCs have in the development of PGDs?

- Ensure that practice efficiency and workload is not affected by the failure of statutory organisations (e.g. CCGs) to approve appropriate PGDs
- Provide advice to practices on PGDs and PSDs.
- Provide advice to practices seeking to write their own PGDs
- Ensure that CCGs do not unreasonably withdraw PGDs or allow them to go out of date without renewal

5. Can non-prescribing nurses administer POMs without a PGD in place?

Yes, a PGD is just one of three methods of permitting administration. The other two, prescriptions or PSDs, are still available. Some employers of Community Nurses ask GPs to fill in administration charts before allowing a nurse to give a drug, although this must be viewed as discretionary as it is not a legal requirement if a prescription providing detailed instructions has been provided.

6. Do PGDs apply to Health Care Assistants (HCAs)?

No. HCAs are not registered healthcare professionals and can only administer prescription only medicines where they have either been prescribed or there is a Patient Specific Direction in place. [The Human Medicines Regulations 2012](#) does not allow HCAs to administer POMs under a PGD.

⁷ www.legislation.gov.uk/ukxi/2012/1916/schedule/16/part/1/made

⁸ www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/Local-PGD-examples/

7. Can PGDs be used for all medicines?

No, PGDs must only include medicines with a UK marketing authorisation. There are limitations but they are unlikely to apply in general practice as you cannot use them for unlicensed drugs such as specials, dressings, abortifacients, or controlled drugs where used to treat addiction.

In addition PGDs should be considered “carefully” for antimicrobials, off licence, black triangle and controlled drugs. (See section 2.1 ‘Considering the need for a Patient Group Direction’ [NICE MPG2].

8. Can PGDs be used in General Practice to administer non-NHS treatment?

Under the [Human Medicines Regulations 2012](#) (Part 3, Ch 12, para 230) NHS GP practices are not permitted to use NHS PGDs to administer treatment for non-NHS circumstances, e.g. Hepatitis B vaccine given on a private basis for travel purposes. NHS practices can however use a private PGD.

9. Can PGDs be used for travel clinics?

PGDs are useful for NHS travel health services as in many practices these are delivered by practice nurses who have a special expertise in that field.

The MHRA state that Regulation 231 of the Human Medicines Regulations allow for the use of PGDs by independent hospitals, clinics and medical agencies. In England, these healthcare providers must be registered with the Care Quality Commission for specific activities such as treatment of disease, disorder or injury.

For England, an independent medical agency is defined as an undertaking which consists of or includes the provision of services by medical practitioners. The term “undertaking” includes any business or profession. The MHRA has taken the view that this means that English GP surgeries registered with the CQC for relevant regulated activities (for example, treatment of disease, disorder or injury,) can develop and sign off their own PGDs for any wholly private services they offer.

In the rest of the UK, a GP surgery would not come within the scope of the term “independent medical agency” because it is more narrowly defined.

If it is not possible to develop or use a PGD, Patient Specific Directions will need to be used in these circumstances.

10. Can a GP sign off a PGD?

A PGD can only be signed off by an authorised body [CCGs, Local authorities, or NHS England] when it applies to an NHS service. However GPs can sign off a PGD for a private service or a private travel clinic even though they cannot do so for their own NHS practice or clinic. Legislation governing authorisation of PGDs in a private setting is covered in the MHRA briefing in Appendix A.

If a doctor is authorising a PGD in a clinical governance capacity on behalf of an authorised body, they should not be involved in development of the PGD or sign off of the clinical content.

11. Can a PCO demand that a practice adopts a PGD for a particular POM?

No. The practice should determine the most appropriate method for the administration of medicines.

12. What if the Authorised body withdraws PGDs for certain medicines?

There is nothing in the legislation that states that authorised bodies have to develop PGDs, they merely have to authorise them. Therefore GP practices can develop their own PGDs and it would be difficult for authorised bodies to justify not approving it if all the conditions have been met and there is a clinical need for the service, as they would not be adhering to their duties to administer and provide health care to the public as set out in the NHS Act 2006.

Practices should, with LMC support, justify to the authorised body, in writing, the reasons why a PGD is needed, quoting the authorised body's duties under the NHS Act and [the Prescription Only Medicines \(Human Use\) Amendment Order 2000](#).

If there are difficulties with the use of or production of PGDs then the practice should use patient specific directions where possible in order to continue providing the service.

13. Who in the practice has to sign a PGD?

The authorising GP has to sign a PGD naming the specific health care professional (HCP) who the PGD will apply to. The GPC also recommends that the HCP acting under the PGD should sign it.

14. Can nurse or pharmacist prescribers issue PSDs?

Yes, nurses and pharmacists may issue a PSD and instruct another HCP to administer the medicine. Naturally, like any other act of authorising a POM, they should have the necessary knowledge and qualifications to authorise that drug.

15. Can PGDs be used to administer Botox?

No. The administration of medicines to paralyse muscles which cause wrinkles (e.g. Botox[®], Vistabel[®] or Dysport[®]) requires assessment of individual patients' suitability and (if the administration is to be delegated to another HCP) PSDs. PGDs or general directions which would apply to any patient with an appointment on a particular day are not sufficient⁹.

Examples

Childhood Immunisation Clinics

When children have been called for vaccinations and non-prescribing nurses are immunising the children, practices have two options:

- for there to be a PSD in place for each patient attending the clinic, in the form of a note in the patient record or a list of those attending the clinic signed by the GP. The note or list must specify which vaccination is due for each child
- the practice to have a PGD in place which allows the nurse to administer the POM.

If HCAs are to be administering the vaccinations note that a PGD cannot be used, PSDs are required.

Vaccinations and Medicines for Travel

If a patient is attending a nurse appointment and requires an NHS vaccination for travel, the most straightforward solution would be for the nurse to be able to administer that vaccination under the authority of a PGD. The GPC would recommend in these circumstances that if a PGD is available and acceptable to the GP, it would be in the practice's interest to have a PGD in place. However, an NHS PGD cannot be used for private immunisations so Rabies, Yellow Fever, Japanese B encephalitis, and Tick Borne encephalitis cannot be administered under an NHS PGD. This also applies to supply of anti-malaria chemoprophylaxis or for any other drugs supplied privately (such as, for example, antibiotics, acetazolamide) in case of disease arising abroad. However English practices who, by definition, will be registered with the CQC, can write and sign off a private PGD for these private travel immunisations.

Opportunistic treatment

If a patient attends a nurse appointment and requires a prescription only medicine, the nurse can decide to administer that treatment under the authority of a PGD rather than obtaining a specific instruction from a GP, indeed opportunistic administration cannot be authorised by a

⁹ *Supply and administration of Botox[®], Vistabel[®] or Dysport[®] and other Injectable medicines in cosmetic procedures*, Medicines and Healthcare products Regulatory Agency, and *Medicine Matters – a guide to mechanisms for the prescribing, supply and administration of medicines*, Department of Health, 2006

PSD, which requires prior assessment by the directing prescriber. The GPC would recommend in these circumstances that if a PGD is available, has been agreed and signed off by the Primary Care Organisation (PCO) and acceptable to the GP, it would be in the practice's interest to utilise a PGD. For example, this may be appropriate in a GP sexual health clinic where immediate supply and administration of emergency hormonal contraception is needed.

Instructions from secondary care

If a patient attends the practice for the administration of a drug specified in a letter from secondary care (e.g. Clexane, Zoladex) then the nurse may regard a letter requesting administration and signed by a prescriber as a PSD and may administer the drug provided that he/she is satisfied that the letter contains sufficient detail to allow this to be done safely, i.e. should include the full name of the drug, dose, route and frequency to be administered as well as the signature of the prescriber. Any uncertainties should be clarified with a prescriber before administration.

Further information can be found in the [PSD FAQs](#) on the NHS Patient Group Directions website.

Further Information and useful links

Medicines Act (1968)

www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1968/cukpga_19680067_en_1

Health Service Circular (HSC 2000/026): Patient Group Directions

webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/PublicationsAndStatistics/LettersAndCirculars/HealthServiceCirculars/DH_4004179

NHS Patient Group Directions (PGD) website

www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/

Department of Health guidance

[https://webarchive.nationalarchives.gov.uk/20120503091608/http://www.dh.gov.uk/en/Managingyourorganisation/Emergencyplanning/DH_4069610\(2011\)](https://webarchive.nationalarchives.gov.uk/20120503091608/http://www.dh.gov.uk/en/Managingyourorganisation/Emergencyplanning/DH_4069610(2011))

[https://www.gov.uk/government/collections/home-office-circulars-2012\(2003\)](https://www.gov.uk/government/collections/home-office-circulars-2012(2003))

Medicines Matters - A guide to mechanisms for the prescribing, supply and administration of medicines (2006)

webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_064325 (sections 2 & 3)

NICE medicines practice guidelines [MPG2] (2013)

www.nice.org.uk/guidance/MPG2

Medicines and Healthcare products Regulatory Agency (MHRA) PGD guidance

www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingandsellingandsupplyingofmedicines/ExemptionsfromMedicinesActrestrictions/PatientGroupDirectionsintheNHS/index.htm

NHS Education for Scotland guidance

www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/prescribing-and-patient-group-direction/patient-group-directions.aspx

Practice Nurse information on the NHS Wales website

<http://www.wales.nhs.uk/sites3/home.cfm?orgid=739>

MHRA Guidance on the development, implementation and review of patient group directions in independent hospitals, medical agencies and clinics, dental clinics and practices, prison healthcare services, police services and defence medical services [previously published on their website].

Background

1. In 1998 a report on the Supply and Administration of Medicines under Group Protocols was published¹ (Patient Group Directions is the legal term for what were known as group protocols). Patient Group Directions (PGDs) are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. The Report recommended that the legal position should be clarified, and in August 2000 the relevant medicines legislation was amended to encompass the national health services (NHS) and those services funded by the NHS that were provided by the private, voluntary or charitable sector.

2. Subsequently, in April 2002 proposals were published to further amend medicines legislation to permit the sale, supply or administration of medicines under PGDs in specified healthcare establishments throughout the United Kingdom provided through the private, charitable or voluntary sector, and in certain UK Crown establishments.

3. PGDs do not extend to independent and public sector care homes or to those independent sector schools that provide healthcare entirely outside the NHS.

4. The majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration of medicines under PGDs should be reserved for those limited situations where this offers an advantage for patient care without compromising patient safety, and where it is consistent with appropriate professional relationships and accountability.

The law

5. The relevant provisions are contained in the Human Medicines Regulations 2012 (SI 2012 No 1916. This can be accessed www.legislation.gov.uk.

Signature requirements for PGDs

6. The patient group direction must be signed by a senior doctor (or, if appropriate, a dentist) and a pharmacist, both of whom should have been involved in developing the direction. Additionally, the PGD must be authorised by the relevant appropriate body as set out in the legislation.

Arrangements for Scotland

7. Independent providers should be aware that in Scotland only independent hospitals and hospices are currently registered under the Regulation of Care (Scotland) Act 2001. As yet a commencement order for independent clinics and independent medical agencies has not been made. Therefore, until the Scottish legislative regime governing the regulation of care services is extended to include independent clinics and medical agencies PGDs can only be set up for use in independent hospitals and hospices. Furthermore, a PGD signed by a provider of an independent health care service registered in England and Wales cannot be used to authorise the supply or administration of medicines by its own staff in Scotland. However, a provider registered in England and Wales can enter into an arrangement with a pharmacist based in a Scottish community pharmacy to operate under a PGD. The same applies to the use of PGDs in England and Wales by a provider registered in Scotland. **Annex A** to this document provides further details about the requirements for authorisation.

8. The qualified health professionals who may supply or administer medicines under a patient group direction are nurses; midwives; health visitors; optometrists; pharmacists; chiropodists; radiographers; orthoptists; physiotherapists, ambulance paramedics, and with effect from 1 June 2010, dental hygienists and dental therapists. They can only do so as named individuals. The legislation specifies that each PGD must contain the following information:

- the name of the business to which the direction applies
- the date the direction comes into force and the date it expires
- a description of the medicine(s) to which the direction applies
- class of health professional who may supply or administer the medicine
- signature of a doctor or dentist, as appropriate, and a pharmacist
- signature by an appropriate organisation
- the clinical condition or situation to which the direction applies
- a description of those patients excluded from treatment under the direction
- a description of the circumstances in which further advice should be sought from a doctor (or dentist, as appropriate) and arrangements for referral
- details of appropriate dosage and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period over which the medicine should be administered
- relevant warnings, including potential adverse reactions
- details of any necessary follow-up action and the circumstances
- a statement of the records to be kept for audit purposes.

Additional guidance

9. The recommendations in the Review Team's Report are emphasised. In particular:

- PGDs should be drawn up by a multi-disciplinary group involving a doctor, a pharmacist and a representative of any professional group expected to supply medicines under the PGD. It is good practice to involve local Drug and Therapeutics Committees, Area Prescribing Committee and similar advisory bodies
- 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
- all professions must act within their appropriate Code of Professional Conduct
- appropriate document(s) should be signed by each member of the multi-disciplinary group, by the representative of the appropriate authorising body and the individual health professionals working under the direction. Generally, a direction should be reviewed every two years. That review should include clinical governance arrangements and an assessment of whether the PGD remains the most effective way of providing the relevant services.

10. There must be comprehensive arrangements for the security, storage and labelling of all medicines. Wherever possible, medicines should be supplied in pre-packs made up by a pharmacist. In particular 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. Names of the health professionals providing treatment, patient identifiers and medicine provided should all be recorded.

Labelling and leaflets for medicines supplied under a PGD

11. Single dose medicines which are not injectables and which are supplied by a healthcare professional under PGD and then immediately self-administered or administered by another person, such as a carer or healthcare worker, in the same room or clinic do not require labelling. This also applies to injectable medicines supplied and administered under a PGD by a healthcare professional.

12. Medicines supplied and taken away by the patient for self-administration or administration by a carer/ another healthcare worker at a later time must be labelled. A patient information leaflet must be supplied in every case whether or not the medicine has to be labelled separately.

13. It is important that the use of any medicine is consistent with the Summary of Product Characteristics for the relevant product (save in special circumstances – see paragraph 13) and any relevant authoritative good practice guidance.

Antimicrobials

14. Particular caution should be exercised in any decision to draw up PGDs relating to antibiotics. Microbial resistance is a public health matter of major importance and great care should be taken to ensure that their inclusion in a direction is absolutely necessary and will not jeopardise strategies to combat increasing resistance. A local microbiologist should be involved in drawing up the PGD. The local Drug and Therapeutics Committee or Area Prescribing Committee, where they exist, should ensure that any such directions are consistent with local policies and subject to regular external audit. **Black triangle drugs and medicines used outside the terms of the Summary of Product Characteristics**

15. Black triangle drugs (i.e. those recently licensed and subject to special reporting arrangements for adverse reactions) and medicines used outside the terms of the Summary of Product Characteristics (e.g. as used in some areas of specialist paediatric care) may be included in PGDs provided such use is exceptional, justified by current best clinical practice and that a direction clearly describes the status of the product. Where the medicine is for children, particular attention will be needed to specify any restrictions on the age, size and maturity of the child. Each PGD should clearly state when the product is being used outside the terms of the SPC and the documentation should include the reasons why, exceptionally, such use is necessary.

Controlled Drugs

16. The use of controlled drugs continues to be regulated under the Misuse of Drugs Act 1971 and associated regulations made under that Act. The Home Office has agreed to allow the supply and administration of substances on Schedule 4 (with the exclusion of anabolic steroids) and all substances on schedule 5 to be included in PGDs. Midazolam (Schedule 3) can also be used under a PGD. From April 2012, nurses and pharmacists, when acting in their capacity as such under a PGD, are authorised to supply, or offer to supply diamorphine and morphine where administration of such drugs is required for the immediate, necessary treatment of sick or injured persons (excluding the treatment of addiction). These amendments remove the restrictions whereby a nurse could only supply or offer to supply diamorphine under a PGD for the treatment of cardiac pain to a person admitted as a patient to a coronary care unit or an accident and emergency department of a hospital.

Other exemptions and restrictions

17. Paramedics, midwives and chiropodists are already exempt from certain requirements of the Human Medicines Regulations. These exemptions, which allow them to administer or supply certain specified medicines without the directions of a doctor will continue and are not affected by the new provisions for PGDs. The administration of radiopharmaceuticals continues to be regulated by the Medicines (Administration of Radioactive Substances) Regulations 1978 and should not be included in patient group directions.

Sharing good practice

18. The PGD website ([NHS Evidence Medicines Information](#)) is the national resource in England both for public and private sector organisations who use or intend to use PGDs and health professionals who work with PGDs or are involved in their development and review. Tools are provided to help users consider whether a PGD would be appropriate for an area of practice that involves the supply or administration of medicines. Another resource is the [National Institute for health and Care Excellence Good Practice Guidance website](#).

Patient Group Directions (PGDs) in the independent healthcare sector and changes to arrangements for registration with the Care Quality Commission (CQC)

19. From 1 October 2010 the Health and Social Care Act 2008 (HSCA) brought about changes in registration for the independent healthcare sector replacing the previous Care Standards Act 2000. The changes meant in England that providers of specified regulated activities are required to register. The CQC no longer registered independent hospitals, clinics and medical agencies.

20. The Human Medicines Regulations 2012 continue to allow independent hospitals, clinics and medical agencies to authorise their own PGDs. They must be registered with the CQC for one of the following regulated activities:

- treatment of disease, disorder or injury
- assessment or medical treatment of persons detained under the Mental Health Act 1983
- surgical Procedures
- diagnostic and Screening procedures
- maternity and midwifery services
- family planning.

21. The Regulations also allow dental practices and clinics who are registered with the CQC for the treatment of disease, disorder or injury and/or diagnostic and screening procedures to authorise PGDs.

22. Registered providers who are independent medical agencies within the meaning of the Human Medicines Regulations 2012 are also able to enter into arrangements with an NHS body to supply and administer medicines under a PGD as part of an NHS funded service. The Agency takes the view that where a PGD is used for NHS/public health funded healthcare under arrangements made with an NHS or public health body the law requires that the PGD is authorised by that body. This applies to PGDs used for the provision of NHS and public health

funded services under arrangements between NHS bodies/local authorities and CQC registered independent medical agencies.

Annex A

23. Persons by whom or on whose behalf a patient group direction used for the provision of health care in non-NHS settings must be signed.

Healthcare provider	Person by whom or on whose behalf the Direction must be signed
An independent hospital, clinic or medical agency (England and Wales only)	The registered provider and if there is a relevant manager for the hospital, clinic or agency that manager
An independent hospital (including a hospice) (Scotland only) NB The current position in Scotland is that PGD's can only be set up for use in independent hospitals and hospices	The registered provider and if there is a relevant manager for the hospital that manager
A nursing home (Northern Ireland only)	The registered provider and if there is a relevant manager for the home that manager
A police force in England or Wales	The chief officer of police for that police force and a doctor who is not employed/engaged or providing services to any police force.
A police force in Scotland	The chief constable of that police force and a doctor who is not employed/engaged or providing services to any police force.
The Police Service of Northern Ireland	The Chief Constable of the Police Service of Northern Ireland and a doctor who is not employed/engaged or providing services to any police force.
The prison service in England and Wales	The governor of the prison in relation to which the health care in question is being provided
The prison service in Scotland	The Scottish Prison Service Management Board
The prison service in Northern Ireland	The Northern Ireland Prison Service Management Board
Her Majesty's Forces	(i) the Surgeon General, (ii) a Medical Director General, or (iii) a chief executive of an executive agency of the Ministry of Defence
Dental Practices and Clinics	By, or on behalf of, the registered provider.

