**Patient Group Direction Template**

This template is based on the version being used to develop the national PGD templates as part of the [SPS National Medicines Governance Do Once programme](https://www.sps.nhs.uk/articles/medicines-governance-do-once-programme/).

Organisations may decide to use this template when developing their PGDs to encourage consistency when national PGD templates are adopted by organisations as they are released.

The template includes guidance on points to be considered locally in italics. Where the text is also in bold this is the text which is usually included in the national PGD templates.

Please refer to the [SPS website](https://www.sps.nhs.uk/) for further PGD resources to support development of PGDs including [NICE Medicines Practice Guidance for Patient Group Directions](https://www.nice.org.uk/guidance/mpg2).

Insert logo of [authorising body](https://www.nice.org.uk/guidance/mpg2/chapter/Recommendations#terms-used-in-the-guideline)

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| This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. |

**PATIENT GROUP DIRECTION (PGD)**

**Supply/Administration of XXX in location/service/organisation**

Version Number X.X

|  |
| --- |
| **Change History** |
| **Version and Date** | **Change details** |
|  |  |

Each organisation using this PGD must ensure that it is formally signed by a senior pharmacist, a senior doctor and any other professional group representatives involved in its review and that it is reviewed in line with the organisations’ PGD governance system. The organisation’s governance lead must sign to authorise the PGD on behalf of the authorising organisation to ensure that this document meets legal requirements for a PGD.

**PGD DEVELOPMENT GROUP**

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| Date PGD template comes into effect:  |  |
| Review date |  |
| Expiry date:  |  |

This PGD template has been peer reviewed by the XXX Short Life Working Group in accordance with their Terms of Reference. It has been approved by the XXX in XXX

**This section MUST REMAIN when a PGD is adopted by an organisation.**

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| **Name** | **Designation** |
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**The PGD template is not legally valid until it has had the relevant organisational approval - see below.**

**Glossary**

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**ORGANISATIONAL AUTHORISATIONS AND OTHER LEGAL REQUIREMENTS**

**This page may be deleted if replaced with a format agreed according to local PGD policy with relevant approvals and authorisation.**

The PGD is not legally valid until it has had the relevant organisational authorisations.

To ensure compliance with the law, organisations must add local authorisation details i.e. clinical authorisations and the person signing on behalf of the authorising organisation. You may either complete details below or delete and use a format agreed according to local PGD policy which complies with PGD legislation and [NICE MPG2 PGD 2017](https://www.nice.org.uk/Guidance/MPG2).

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| --- | --- | --- | --- |
| **Name**  | **Job title and organisation**  | **Signature** | **Date** |
| **Senior doctor**  |  |  |  |
| **Senior pharmacist** |  |  |  |
| **Senior representative of professional group using the PGD**  |  |  |  |
| **Person signing on behalf of** [**authorising body**](http://publications.nice.org.uk/patient-group-directions-gpg2/appendix-a-glossary#authorising-body) |  |  |  |

It is the responsibility of the provider organisation to ensure that all legal and governance requirements for using the PGD are met.

To meet legal requirements, authorising organisations must add an Individual Practitioner Authorisation sheet or List of Authorised Practitioners. This varies according to local policy and how the service is managed but this should be a signature list or an individual agreement.

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medication(s) listed only in accordance with the PGD.

**ORGANISATIONS MAY ALSO ADD:**

* Local training and competency assessment documentation
* Other supporting local guidance or information
* Links to local PGD Policy and other supporting guidance
* Audit requirements

Any reference to a Trust protocol (either clinical to be followed as part of the administration of a medication with the PGD or for any other purpose) must be referenced and hyperlinked to ensure the practitioner acting under the PGD has direct access to the protocol for reference.

1. **Characteristics of staff**

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| **Qualifications and professional registration** | *Examples:** + - * *NMC registered nurse has a current contract of employment with organisation name*
			* *HCPC registered podiatrist has a current contract of employment with organisation name.*

*This section may include specialist qualifications, such as emergency nurse practitioner but must reflect the registered profession within the PGD legislation (i.e. Registered nurses or paramedics working in an Emergency Practitioner role with a current contract of employment with organisation name)* |
| **Initial training** | *Successful completion of specified courses may include:** + - * *local training in the use of PGDs/medicines management*
			* *training which enables the practitioner to make a clinical assessment in order to establish the need and supply the medicine according to the PGD, e.g. smoking cessation*
			* *immunisation and vaccination training (theoretical and practical) as per local policy.*

***The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate training and successfully completed the competencies to undertake clinical assessment of individuals leading to diagnosis of the conditions listed.*** |
| **Competency assessment** | *Consider how competency will be assessed and by whom. This could be a self-declaration of competency. You do not need to add much detail in the PGD itself but may wish to refer to any key points or training. Appendix A gives an example of an authorisation recording sheet – local versions/electronic systems may be used.**Staff operating under this PGD are encouraged to review their competency using the* [*NICE Competency Framework for health professionals using patient group directions*](https://www.nice.org.uk/guidance/mpg2/resources)***Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.*** |
| **Ongoing training and competency** | *Specify competences with evidence of annual updates as required, for example, actively taking part in CPD and annual individual performance reviews.* *Specify mandatory training, such as CPR/life support/anaphylaxis competences, with evidence of updates as required.* *Specify experience or competences for working under the PGD, such as regular training and updating in safeguarding children and vulnerable adults.**Organisation PGD or medication training as required by employing Trust/organisation.* |
| ***The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies****.*  |

1. **Clinical condition or situation to which this PGD applies**

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| **Clinical condition or situation to which this PGD applies** | *Define situation/condition/indication* |
| **Criteria for inclusion**Use BNF/BNFC/SPC. Take into account any clinical guidelines or policies that are available locally or nationally, e.g. BASHH/NICE/JCVI | *Use bullet points to list inclusions.** *Consent gained – if under 16 years consider requirements for consent.*
* *Define age range/sex e.g. individuals over 12 years old.*
* *Do you include pregnant individuals?*
* *Do you include breast feeding individuals?*
* *Include clinical criteria. Must reflect local and/or national clinical guidelines or policies where available.*
 |
| **Criteria for exclusion** | *Use bullet points to list exclusions.** + - * *Consent not gained*
			* *Who is not eligible to receive the medicine, e.g. upper and lower age limits?* *State cut-off points for exclusion/limitations for service, i.e. to age of included groups, e.g. ‘children under 2 years old’ not just ‘children’.*
			* *Must reflect local and/or national clinical guidelines or policies where available.*

*Reasons for exclusion may include:** + - * *age*
			* *concurrent conditions*
			* *concurrent treatment – such as  taking medicines which may give rise to toxicity or the need for increased dose if taken with medicine in PGD*
			* *previous local or systemic reactions to the medicine*
			* *known hypersensitivity to the active ingredient or to any component of the product - see* [*Summary of Product Characteristics*](https://www.medicines.org.uk/emc)
			* *pregnancy and/or breast feeding*
			* *anything else stated in the SPC that may give reason for exclusion of specific individuals*
			* *severity of renal/hepatic insufficiency.*
 |
| **Cautions including any relevant action to be taken** | *Always explain cautions and action to be taken, e.g. immunisation should be postponed in individuals with acute febrile illness/infection.**Note: if the decision for action is to consult with a doctor/dentist, you must exclude this group of individuals.**Use bullet points to list cautions and the action to be taken.** + - * *Must reflect local and/or national clinical guidelines or policies where available.*
			* *List clinically significant medicines interactions which do not exclude individuals but where there may be action to be taken, e.g. closer monitoring individuals.*
			* *Enter specific details of action to be taken, e.g. advise diabetic individuals that they may need to monitor blood glucose levels more closely at start of treatment. In these cases, PGD will also need to state the relevant information in the further advice section.*
			* *Include anything else stated in the SPC that may give reason for caution for specific individuals but does not exclude them (e.g. advice on breastfeeding).*
 |
| **Action to be taken if the individual is excluded** | *Consider arrangements required to identify and contact an appropriate clinician or prescriber during the consultation should the need arise, e.g. access to appropriate emergency advice and assistance.** + - * ***Record reasons for exclusion in an individual’s clinical record***
			* ***Advise individuals on alternative treatment***
			* ***Refer to another clinician or prescriber if appropriate***
 |
| **Action to be taken if the individual or carer declines treatment** | *Add details of action to be taken if a individual is excluded, i.e. referral/records to be kept.** + - * ***Document advice given***
			* ***Advise individual on alternative treatment***
			* ***Refer to another clinician or prescriber if appropriate***
 |
| **Arrangements for referral for medical advice** | *Add details of action to be taken, i.e. discussion of potential consequences/referral/records to be kept.****Refer to the appropriate clinician or prescriber in the care pathway*** |

1. **Description of treatment**

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| **Name, strength & formulation of drug** | *Generic name (brand only if relevant), strength/s and formulation/s.* |
| **Legal category** | *For example, prescription-only medicine (POM).* |
| **Route / method of administration** | *To avoid errors, state this in full and do not use Latin or abbreviations, e.g. ‘oral’ not ‘p.o.’/’eye drops’ not ‘guttae’/‘single dose’ not ‘stat’* |
| **Indicate any off-label use****(if relevant)** | *Add reference/note to support use in unlicensed/off label circumstances, e.g. best practice advice given by BASHH is used for this PGD and may vary from the manufacturer’s summary of product characteristics.* *Consider including the below statements if appropriate:** *Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with pharmacy/Medicines Management.*
* *Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the medicine is being offered in accordance with national guidance but that this is outside the product licence.*
 |
| **Dose and frequency of administration** | * + - * *State dose in full. Do not use Latin or abbreviations e.g. ‘stat’ or ‘tds’.*
			* *State practical information, such as ‘after food’ or ‘dissolved in water’.*
			* *Decide on format to express dose, especially in children. For example, if using mg/kg will doses be rounded up or down to the nearest spoonful?*
			* *For medications supplied to individuals, express dose format to match that of the pharmacy label, e.g. one tablet to be taken three times a day.*
 |
| **Duration of treatment** | *This may be specific, for example, five days for an antibiotic or no more than x number of days for an analgesic.* *Consider practical issues relating to dose and quantity, such as rounding up or down to nearest appropriate pack size if required and making sure appropriately labelled packs are available for the duration of treatment.* |
| **Quantity to be supplied**  | *Complete if for supply.* |
| **Storage** | ***Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website:*** [www.medicines.org.uk](http://www.medicines.org.uk) |
| **Drug interactions** | ***All concurrent medications must be checked for interactions. The following interactions have been identified as clinically significant:**** + - * ***X***
			* ***Y***
			* ***Z***

***A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk***  |
| **Identification & management of adverse reactions** | ***A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website:*** [***www.medicines.org.uk***](http://www.medicines.org.uk) ***and BNF*** [***www.bnf.org***](http://www.bnf.org)***The following possible adverse effects are commonly reported with XXX (but may not reflect all reported adverse effects):**** + - * ***A***
			* ***B***
			* ***C***

***A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website:*** [***www.medicines.org.uk***](http://www.medicines.org.uk) |
| **Management of and reporting procedure for adverse reactions** | * + - * ***Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on:*** [***https://yellowcard.mhra.gov.uk***](https://yellowcard.mhra.gov.uk)
			* ***Record all adverse drug reactions (ADRs) in the individual’s clinical record.***
			* ***Report via organisation incident policy.***
			* *If anaphylaxis management may be required include this information here (e.g. adrenaline to be held/resuscitation team details)*
 |
| **Written information to be given to individual or carer** | ***Give marketing authorisation holder's product information leaflet (PIL) provided with the product.***  |
| **Advice / follow up treatment** | ***Inform the individual/carer of possible side effects and their management.******The individual/carer should be advised to seek medical advice in the event of an adverse reaction.*** |
| **Records** | ***Record:*** * + - * *that valid informed consent was given*
			* *name of individual, address, date of birth and GP with whom the individual is registered (if relevant)*
			* *name of registered health professional*
			* *name of medication supplied/administered*
			* *date of supply/administration*
			* *dose, form and route of supply/administration*
			* *quantity supplied/administered*
			* *batch number and expiry date (if applicable)*
			* *advice given, including advice given if excluded or declines treatment*
			* *details of any adverse drug reactions and actions taken*
			* *supplied via Patient Group Direction (PGD)*

***Records should be signed and dated (or a password controlled e-records).*** ***All records should be clear, legible and contemporaneous.******A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.*** |

1. **Key references**

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| **Key references**  | * + - * *Electronic Medicines Compendium* [*http://www.medicines.org.uk/*](http://www.medicines.org.uk/)
			* *Electronic BNF* [*https://bnf.nice.org.uk/*](https://bnf.nice.org.uk/)
			* *NICE Medicines practice guideline “Patient Group Directions” <https://www.nice.org.uk/guidance/mpg2>*
 |

**Appendix A – Example registered health professional authorisation sheet (example – local versions/electronic systems may be used)**

**PGD Name/Version Valid from: Expiry:**

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

**Registered health professional**

By signing this Patient Group Direction you are indicating that you agree to its contents and that you will work within it.

Patient Group Directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

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| **I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.** |
| **Name** | **Designation** | **Signature** | **Date** |
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**Authorising manager**

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| **I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of INSERT NAME OF ORGANISATION for the above named health care professionals who have signed the PGD to work under it.** |
| **Name** | **Designation** | **Signature** | **Date** |
|   |   |   |   |

**Note to authorising manager**

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.