PGD template with guidance notes

NICE has developed a patient group directions (PGD) template to support commissioners and providers of NHS services to develop local PGDs that are in line with current legislation and NICE medicines practice guideline 2 (MPG2): *Patient group directions*.

This document uses the NICE PGD template and adds guidance notes to help people and organisations develop good-quality PGDs. These guidance notes are not exhaustive but provide sample text for people with little experience of writing PGDs.

This is a reference source only. We have included links from the NICE PGD template to signpost you to relevant information. We have also added links to other information, eg, the NHS PGD website FAQs.

When developing your PGD you must also refer to MPG2 which contains other important information not covered here.

We use the following abbreviations in the document:

BASHH – British Association of Sexual Health and HIV

NICE – National Institute of Health and Care Excellence

FSRH – Faculty of Sexual and Reproductive Health

JCVI – Joint Committee on Vaccination and Immunisation 'Green Book'

The best PGDs are succinct and practical documents. They provide enough information to be legal and to ensure successful implementation, but not so much information that users do not read them. For example, it is better to signpost to national and local guidelines than to add the guidelines as appendices.

Key

Blue highlighted text – this is text that you need to change
Blue text – guidance notes

Insert logo of authorising body

Additional organisational logo(s) as agreed locally

This patient group direction (PGD) must only be used by registered health 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

for the supply and/or administration[1] of

name of medicine

by registered health professional group(s) for

condition / situation / patient group

in location/service/organisation

Version number: number

1 Change history

Version number	Change details	Date

[1] Delete as appropriate.

Reference Number:
Valid from:
Review date:
Expiry date:

2 Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS PGD website FAQs.

3 PGD development

Refer to the NICE PGD competency framework for people developing PGDs.

Name	Job title and organisation	Signature	Date
Lead author			
Lead doctor (or dentist)			
Lead pharmacist			
Representative of other professional group using PGD			
Other members of the PGD working group			

4 PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs.

Name	Job title and organisation	Signature	Date
Senior doctor (or dentist)			
Senior pharmacist			
Senior representative of professional group using the PGD			
Person signing on behalf of authorising body	For example, clinical governance or patient safety lead, who has designated responsibility for signing PGDs on behalf of the authorising body, in line with legislation.		

5 PGD adoption by the provider[2]

Refer to the NICE PGD competency framework for people authorising PGDs.

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant.	For example, superintendent pharmacist, clinical director or GP lead.		

6 Training and competency of registered health professionals

Refer to the NICE PGD competency framework for health professionals using PGDs.

	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	**Examples** NMC registered nurse/HCPC registered podiatrist has a current contract of employment with xxx. This may include specialist qualifications, such as emergency nurse practitioner.
Initial training	Successful completion of specified courses may include: • training in the use of PGDs • training which enables the practitioner to make a clinical assessment in order to establish the need and supply the medicine according to the PGD, eg, smoking cessation • immunisation and vaccination training (theoretical and practical) as per local policy.
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.
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.

[2] Delete section if not relevant.

7 Clinical condition

Clinical condition or situation to which this PGD applies	Define situation/condition/indication, eg, immunisation against seasonal flu vaccination.
Inclusion criteria Use *BNF*/*BNFC*/SPC. Take into account any clinical guidelines or policies that are available locally or nationally, eg, BASHH/NICE/JCVI.	Use bullet points to list inclusions. • Define age range/sex, eg, patients over 12 years old. • Do you include pregnant women? • Do you include breast feeding women? • Include clinical criteria. Must reflect local and/or national clinical guidelines or policies where available.
Exclusion criteria Consider SPC sections 4.3-4.7. A caution, rather than a contraindication, in the SPC may also result in exclusion of some patients so they can be individually assessed by a prescriber.	Use bullet points to list exclusions. • Who is not eligible to receive the medicine, eg, upper and lower age limits? • Must reflect local and/or national clinical guidelines or policies where available. Reasons for exclusion may include: • age • concurrent conditions • concurrent treatment – such as patients taking medicines which may give rise to toxicity or the need for increased dose (eg, salbutamol PGD exclusion would be patients taking beta-blockers, as beta-blockers can induce asthma and will also prevent the action of salbutamol) • previous local or general reactions to the medicine • hypersensitivity to the medicine or any of its ingredients • pregnancy and breast feeding • anything else stated in the SPC that may give reason for exclusion of specific patients • degrees of renal/hepatic insufficiency. State cut-off points for exclusion/limitations for service, ie, to age of patient groups, eg, ‘children under 2 years old’ not just ‘children’.

Cautions (including any relevant action to be taken)	Always explain cautions and action to be taken, eg, immunisation should be postponed in patients with acute febrile illness/infection. This section is for additional information for the practitioner to consider, for example (for a vaccine), ensure emergency drugs and equipment, including adrenaline, are available for the treatment of anaphylaxis and emergencies, according to local policy. Note: if the decision for action is to consult with a doctor/dentist, you should exclude this group of patients. • 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 patients but where there may be action to be taken, eg, closer monitoring. • Enter specific details of action to be taken, eg, advise diabetic patients that they may need to monitor blood sugars more closely at start of treatment. In these cases, you will also need to add the relevant information in the patient advice section. • Include anything else stated in the SPC that may give reason for caution for specific patients but does not exclude them (but see note opposite).
Arrangements for referral for medical advice	Consider arrangements required to identify and contact an appropriate medical officer or other independent prescriber during the consultation should the need arise, eg, access to appropriate emergency advice and assistance. In some cases this could be as simple as dial 999.
Action to be taken if patient excluded	Add details of action to be taken if a patient is excluded, ie, referral/records to be kept.
Action to be taken if patient declines treatment	Add details of action to be taken, ie, discussion of potential consequences/referral/records to be kept.

8 Details of the medicine

Name, form and strength of medicine *Include ▼for black triangle medicines*	Agree a local style for clear presentation of this information, eg, express strength and form in *BNF* style or as specified in SPC.
Legal category	For example, prescription-only medicine (POM).
Indicate any off-label use (if relevant)	Add reference/note to support use in unlicensed/off-label circumstances, eg, best practice advice given by BASHH is used for this guidance and may vary from the manufacturer's summary of product characteristics. You should have already considered local policy and whether this use needs approval by a local prescribing committee. You may wish to note this here.
Route/method of administration	To avoid errors, state this in full and do not use Latin or abbreviations, eg, 'oral' not 'p.o.'/'eyedrops' not 'guttae'/'single dose' not 'stat'.
Dose and frequency	• State dose in full. Do not use Latin or abbreviations eg, '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 POMs supplied to patients, express dose format to match that of the pharmacy label, eg, one tablet to be taken three times a day. • For general sales list (GSL) and pharmacy (P) medicines to be taken away, you do not need to state specific dose in the PGD but at minimum should say see pack for details of appropriate dose. • See PGD website FAQ on labelling POMs. • See PGD website FAQ on labelling GSL and P medicines.
Quantity to be administered and/or supplied	Be specific about quantity and whether the PGD is for supply or administration or both, eg, 3 x 21 supply only. Do not just state OP or one original pack.

Maximum or minimum treatment period	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.
Adverse effects	• Use bullet points to clearly list the most common side-effects and any potential serious symptoms the practitioner or patient needs to look out for. • Refer to SPC/*BNF* and any Medicines and Healthcare products Regulatory Agency (MHRA) advice. • Add in order of frequency, eg, common (more than 1 in 100 people). This list may not represent all reported side-effects of this medicine. Refer to the most current SPC for more information. If the medicine is a ▼(black triangle) product, all suspected adverse effects should be reported to the MHRA. Refer to use of the yellow card system to report serious adverse drug reactions directly to the MHRA. You can add additional action to be taken in the event of unexpected adverse reactions, eg: • if necessary seek appropriate emergency advice and assistance • make a note in the individual's clinical record and inform appropriate doctor/independent nurse prescriber • complete incident procedure if adverse reaction is severe (refer to local organisational policy).

Records to be kept	List what must be recorded (note there are certain regulatory standards that must be followed, eg, NMC record keeping standards, so make sure these standards can be met): • patient inclusion or exclusion from PGD • 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 • 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.

9 Patient information

Written information to be given to patient or carer	Examples • Provide manufacturer's patient information leaflet (compulsory for supply and good practice for administration). • Provide any other named information leaflet eg, Family Planning Association leaflet on the related topic. • Advice to be given (if any) if medicine is being used off-label. • State any further instructions to aid compliance. • Counselling points, eg, do not drive for two hours after administration of dilating eye drops, or additional information regarding potential interactions and action to be taken. • Storage or expiry information, eg, store in a fridge. • Practical advice on self-care if appropriate, eg, offer condoms and advise on safer sex practices. • Advice on recognising side-effects and what to do, such as advice on the prevention and management of fever and local reactions and other adverse effects. • Advice on where to seek help if treatment fails or condition worsens. • Consider any other information that would be helpful to the patient at this point of their care, eg, signposting to local self-help groups/issue of an information prescription. • Referral details for any other support the patient may require.
Follow-up advice to be given to patient or carer	Enter requirements, eg, clinical observations after administration/letter to GP/further appointments/other protocols, eg, follow local protocol for chlamydia follow-up and partner notification.

10 Appendices

Appendix A Key references

Examples

1. NICE guideline
2. Summary of product characteristics (include date of revision of text)
3. *British National Formulary* (including number and year)
4. Associated service level agreement if relevant (eg, in community pharmacy services)
5. Local guidelines/national guidelines
6. Journal/other references (use Vancouver reference style)
7. Professional regulator or professional-specific guidance, eg, NMC record keeping guidance

Appendix B Health professionals' agreement to practise

Insert statement to be signed by individual health professionals agreeing to practice under the PGD.

For example:

I have read and understood the patient group direction and agree to supply and/or administer this medicine only in accordance with this PGD.

Name of health professional	Signature	Senior representative authorising health professional	Date
		This may be a designated manager of the service. See NICE recommendation 2.7.1.	

Other appendices may be added as agreed locally, for example, a checklist to be used by practitioners/list of brands that may be supplied, eg, brands of combined oral contraceptives.