



Process for local authorisation and implementation of SPS national Patient Group Direction (PGD), protocol and written instruction (WI) templates

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Process for local authorisation and implementation of SPS national PGD, protocol and WI templates

Audience

NHS organisations and healthcare services commissioned by either the NHS or local authorities in England whose role involve working with legal mechanisms including PGDs, protocols and WIs (e.g., PGD authorisation bodies; PGD users).

Purpose

To describe the local process necessary to authorise and implement national templates developed by the Specialist Pharmacy Service (SPS) for providers of publicly funded services in England.

Definitions and explanation of any terms used

National templates – the term national templates in this document only refers to those templates developed by SPS. Other national PGDs such as immunisation PGDs developed by UKHSA are outside the scope of this document.

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Approved by Medicines Governance Do Once (MGDO) Programme Board April 2024

1. Background

A Patient Group Direction (PGD) is a legal mechanism which allows certain registered healthcare professionals to supply and/or administer specified medicines to pre-defined groups of individuals, without a prescription.¹

In his second report published in May 2018 Lord Carter identified significant duplication of effort across NHS organisations producing PGDs.²

The report recommended that NHS England's Specialist Pharmacy Service (SPS) develop a national 'Do Once' system for essential governance documentation including PGDs.

2. Decision to adopt SPS national templates

SPS has developed national templates with relevant professional bodies/colleges and nationally recognised experts to facilitate the safe and efficient supply, use, and administration of medicines. The PGD templates have been produced in line with legislation, national guidance, recommendations and acknowledged best clinical practice. The templates are intended to support, not substitute relevant national guidance and as such should always be used in practice alongside supporting guidance.

Organisations are strongly encouraged to adopt national templates where appropriate, with the aim of releasing significant local resource to be redeployed on optimising outcomes from medicines use. In addition, adoption will ensure medicines use is consistent with national guidance and acknowledged best clinical practice.

3. Authorisation

Whilst the national templates have been developed by clinical experts and approved by the relevant national body appropriate to the clinical pathway they require the local clinical authorisation of a doctor (or dentist) and pharmacist (see section 3.1); in addition they must be authorised by a body which is legally able to authorise the PGD/WIs before they are used. **This responsibility lies with the organisation implementing the templates.**

3.1 Clinical signatories

The national PGD templates require local clinical authorisation by a doctor (or dentist) and a pharmacist who must both sign the PGD(s) and the WI template the signature of a doctor. It is good practice that the PGD is also signed by a representative of the professional group who will be operating under the PGD. When acting as a doctor, dentist or pharmacist signatory these professionals must confirm that the clinical and pharmaceutical content is accurate and supported by the best available evidence and is in line with any local guidance – any training and competency should must be considered. Further guidance on the authorisation of PGDs and the roles and responsibilities of signatories is available on the SPS website.^{5,6}

3.2 Organisations that can authorise PGDs

In the NHS in England, the organisations who can authorise PGDs for use are:

- Integrated Care Boards (ICBs)
- local authorities.
- NHS trusts or NHS foundation trusts.
- NHS England.
- UK Health Security Agency (UKHSA)

Once the decision has been made locally to adopt a national PGD template and this has been locally clinically signed as outlined above, each organisation must formally authorise each PGD according to their clinical governance processes before it can be used. This is in line with The Human Medicines Regulations (HMR) 2012 Schedule 16 Part 2.³

The PGD is not legal or valid without this authorisation.

3.3 Organisations that cannot authorise PGDs

Where an NHS or local authority publicly funded service is commissioned to be provided by an organisation that is unable to legally authorise the PGD (any organisation outside of the list above) then the commissioning organisation must authorise the PGD.⁴

Further guidance on the authorisation of PGDs, PGD use in complex commissioning scenarios and the roles and responsibilities of signatories is available on the SPS website.^{4,5,6,7}

4. What organisations must do with SPS national templates

The organisation adopting the national template must review them following local governance processes. Any text highlighted in blue on the templates must be reviewed against local process, policy and guidance and amended/completed as appropriate.

The templates state the dates the template is valid from and to and when it was approved by the relevant national body. Organisations must add dates to the template to state when the template is valid for use within the organisation and when it will expire. It is recommended that the expiry date given does not exceed that of the SPS template, as it will have been updated at this point.

As previously detailed the national PGD templates must be clinically authorised by a doctor (or dentist) and a pharmacist. It is good practice that the PGD is also signed by a representative of the professional group who will be operating under the PGD.

Authorising organisations must authorise the PGD in line with The Human Medicines Regulations (HMR) 2012 Schedule 16.³

Organisations operating under the PGD/WI must maintain a list of approved practitioners authorised to work under the PGD/WI (note a template authorisation sheet is included in each of the national templates, but organisations may use their own format if preferred).

5. Altering or amending the SPS national templates

The SPS national templates are written in alignment with relevant national guidance to be applicable to a wide range of services, clinical environments and patient cohorts. Therefore, organisations may need to locally adapt the content to meet the needs of their local populations/service model and other aspects such as laboratory reporting systems.

However, it is advised that the following sections are not altered or amended by the authorising organisations (apart from highlighted text – see below) as they have been reviewed by subject matter experts in line with national guidance and approved by national professional bodies:

- Clinical condition
- Description of treatment
- Key references

As detailed in section 4 any text within the national templates highlighted in blue must be reviewed and adapted to reflect local process, policy and guidance. For example, organisations can narrow the choice of products to be supplied, used or administered under the template (for example selection of oral contraceptive brand) or determine the healthcare professions authorised to operate under it (see section 7).

Organisation may, if they wish, transfer the contents of the template into their own local template, but SPS request that they acknowledge this national work within the document.

Organisations must be aware that

6. Organisations who can adopt the SPS national templates

The SPS national templates are intended for adoption by NHS organisations or NHS commissioned healthcare services as well as healthcare services commissioned by local authorities in England.

If anyone outside of the above, such as private providers providing a private service or organisations in the devolved nations, wishes to adopt the national templates produced by SPS, they are able to do. However, they should be aware that they have been written with the intention of use within NHS/publicly funded healthcare services within England and any organisation outside of these services/England using these templates must be mindful of this.

7. Registered health professionals who can operate under SPS national PGD templates

To maximise the relevance of these documents on a national scale all registered health professionals allowed to work under a PGD by the legislation are included, where appropriate.³

Individual organisations can limit the professions who may operate under the PGD by adapting the 'Characteristics of Staff' section.

Individual registered health professionals must be authorised by name under the current version of the PGD before working according to it – this is the responsibility of the employing organisation.

8. Responsibilities

8.1 Responsibilities of organisations authorising SPS national templates

Organisations listed in the legislation as able to authorise PGDs will:

- Adapt the SPS national template, completing the sections highlighted in blue to reflect local process, policy and guidance.
- Clinically sign the national PGD template or ensure the templates have been appropriately signed where this has been undertaken by an externally commissioned provider
- Authorise national templates according to their clinical governance process.
- Document any changes made to the content of the national template to reflect local requirements in line with local development processes.
- Publish final signed version of the document as appropriate.

8.2 Responsibilities of organisations whose staff work under locally authorised SPS national templates

Organisations using national templates will:

- Have a communications plan in place to support the dissemination of documents and their implementation in clinical area(s). This also includes all updates published during a document's valid period - organisations must check that they are using the current version of the template as amendments may become necessary prior to the published expiry date. Current versions of national templates for authorisation can be found at www.sps.nhs.uk
- Ensure staff working under the authorised version of the document are appropriately trained and competent.
- Identify a senior, responsible person(s) from within the service to authorise named, registered health professionals to practise under the authorised document.
- Ensure medicines protocols and policies are in place to include arrangements for the security, storage and labelling of all medicines administered or supplied. There must be a secure system for recording and monitoring how medicines are used.
- Be responsible for overall organisational governance for example by including the process of adopting SPS national templates in the local policy and by auditing and monitoring use in line with NICE PGD Medicines practice guideline.¹

8.3 Responsibilities of SPS during the lifetime of SPS national templates

SPS will:

- Publish national templates on www.sps.nhs.uk
- Communicate the release of a new template via:
 - email of the SPS weekly bulletin to the people registered on the SPS website;
 - LinkedIn (NHS Specialist Pharmacy Service)
 - the [Medicines Awareness Service](#) bulletin
- Alert of changes made during the lifetime of a template via the above channels.
- Review templates in advance of their expiry or whenever deemed necessary due to changes to supporting guidance/SPCs.

9. Retention of documentation

Documentation should be retained by organisations in line with the advice given in the SPS document 'Retaining legal mechanism documentation.'⁷

10. More information

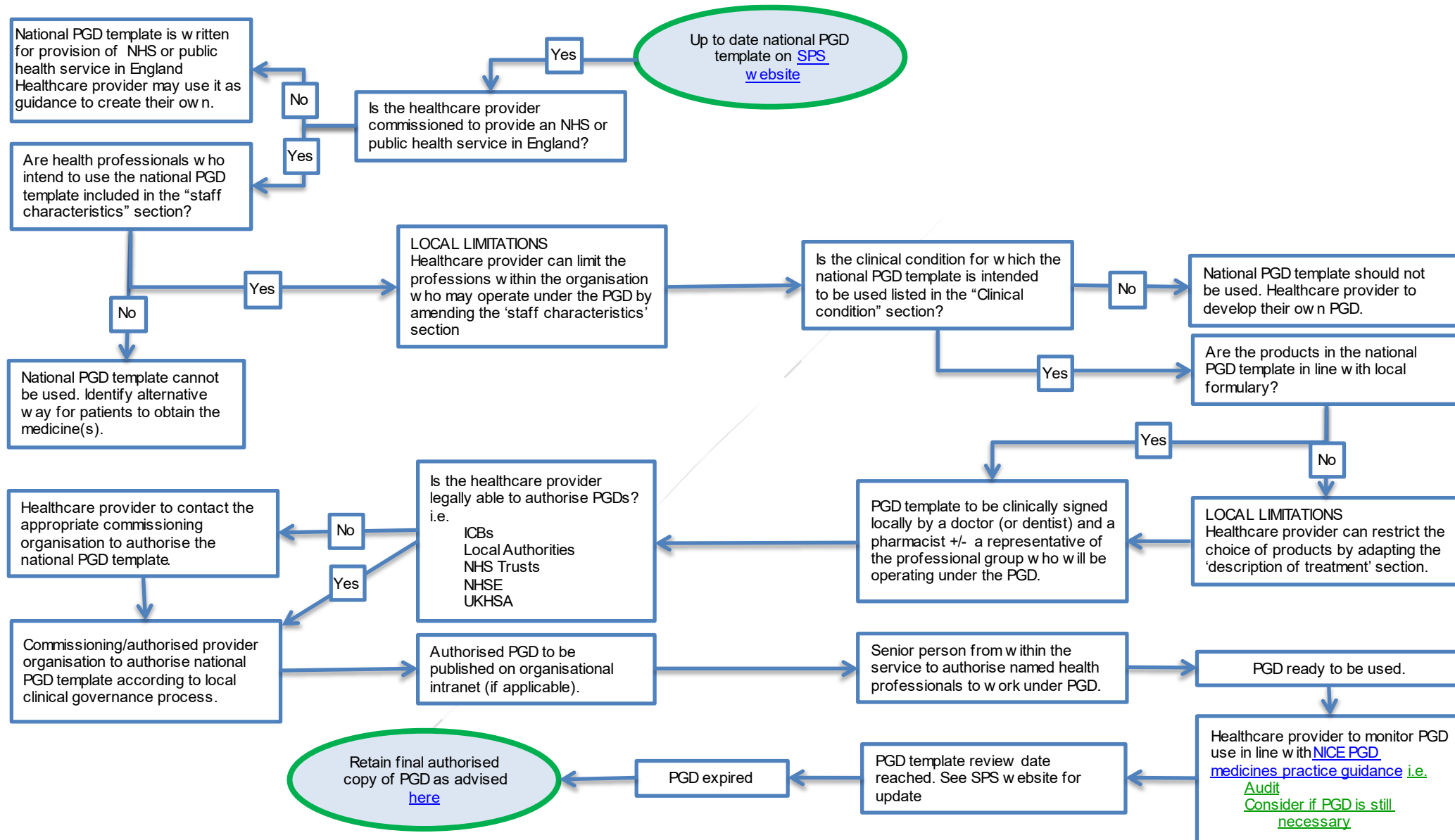
Further guidance is available on the [SPS website](#).

Any concerns regarding the content of this document or national templates should be addressed to: lnwh-tr.sps-pgd@nhs.net

11. References

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6. Patient Group Directions in Complex Commissioning Scenarios SPS
<https://www.sps.nhs.uk/articles/patient-group-directions-in-complex-commissioning-scenarios/> (accessed 11/01/24)
7. Retaining legal mechanism documentation [SPS https://www.sps.nhs.uk/articles/retaining-legal-mechanism-documentation/](https://www.sps.nhs.uk/articles/retaining-legal-mechanism-documentation/) (accessed 11/01/24)





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