Process for authorisation and implementation of SPS national Patient Group Direction (PGD) templates

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Audience

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

Purpose

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

Definitions and explanation of any terms used

National Patient Group Direction (PGD) templates – the term national PGD templates in this document only refers to those developed by SPS. Other national PGDs such as immunisation PGDs developed by PHE are outside the scope of this document.

Contents

1. Background

A Patient Group Direction (PGD) allows certain registered healthcare professionals to supply and/or administer specified medicines to pre-defined groups of patients, 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 national PGD templates

SPS has developed national PGD templates with relevant national professional bodies and 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.

Organisations are strongly encouraged to adopt national PGD 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. For a summary of all steps involved in the decision of adopting a national PGD templates see Appendix 1.

3. Authorisation

Whilst the national PGD templates have been developed by clinical experts and approved by the relevant national body appropriate to the clinical pathway they require clinical signatures from 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 PGDs before they are used. **This responsibility lies with the organisation implementing the PGDs.**

3.1 Clinical signatories

The national PGD templates require local clinical authorisation 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. When acting as a doctor, dentist or pharmacist signatory these professionals must establish that the clinical and pharmaceutical content is accurate and supported by the best available evidence – 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 their own 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 local, formal authorisation.

3.3 Organisations that cannot authorise their own PGDs

Where a NHS or local authority publicly funded commissioned service is provided by an organisation that is unable to legally authorise the PGD (any organisation outside of the list above) then the appropriate commissioning organisation should 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 must organisations do with national PGD templates?

The organisation adopting the national PGD templates 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 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.

The PGD 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 PGD to state when the PGD 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 PGD template.

Authorising organisations must authorise the PGD in line with The Human Medicines Regulations (HMR) 2012 Schedule 16. [3]

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

5. What can be altered or amended in national PGDs?

As the national PGDs are templates they can be locally adapted as required to meet local requirements. 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 PGD 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 PGD (for example selection of oral contraceptive brand) or determine the healthcare professions authorised to operate under the PGD (see section 7).

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

6. Which organisations can work under national PGD templates?

The national PGD 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 PGD templates produced by SPS, they are able to do so but should be aware that they have been written with the intention of use within NHS/publically funded healthcare services within England and any organisation outside of these services/England using these templates must be mindful of this.

7. Which health professionals can operate under national PGDs?

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 national PGD templates

Organisations listed in the legislation as able to authorise PGDs (see paragraph 3.1) will:

- Adapt the national PGD template, completing the sections highlighted in blue to reflect local process, policy and guidance.
- Clinically sign the national PGD template.
- Authorise national PGD templates according to their clinical governance process.
- Document any changes made to the content of the national PGD template to reflect local need in line with local PGD development processes.
- Publish final signed version of the PGD on an intranet (if appropriate).

8.2 Responsibilities of organisations using national PGD templates

Organisations using national PGD templates will:

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

8.3 Responsibilities of registered health professionals practicing under national PGD templates

In addition to the list of responsibilities of registered health professionals using PGDs listed in the NICE PGD medicines practice guideline[1], registered health professionals using national PGD templates will also need to:

- Ensure that the PGD is appropriately authorised and signed. It is neither valid nor legal without this.
- Be authorised by name to practise under the PGD by a senior, responsible person from within the service they work before working according to it. This is a legal requirement.
- Undertake organisation approved training and successfully complete the competencies to undertake clinical assessment of patients leading to diagnosis of the conditions listed in the PGD.
- Have read and understand the context and content of the PGD.
- Sign the appropriate documentation in the 'Registered health professional authorisation sheet' which includes a declaration of training and competence to work under that particular PGD.
- Be personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD.
- Check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of SPS PGD templates for authorisation can be found at www.sps.nhs.uk

8.4 Responsibilities of SPS during the lifetime of national PGD templates

SPS will:

- Publish PGD templates on www.sps.nhs.uk
- Communicate the release of a new PGD templates via email to the people registered on the SPS website; via Twitter @NHS_SPS and via the Medicines Awareness Service bulletin

- Alert of changes made during the lifetime of a PGD template via email to the people registered on the SPS website; via Twitter @NHS_SPS and via the Medicines Awareness Service bulletin
- Review PGD templates that are about to expire or whenever deemed necessary
- Have an updated work plan available on www.sps.nhs.uk

9. Retention of PGD documentation

PGD documentation should be retained by organisations in line with the advice given in the SPS document 'Retaining PGD documentation'.[8]

10. More information

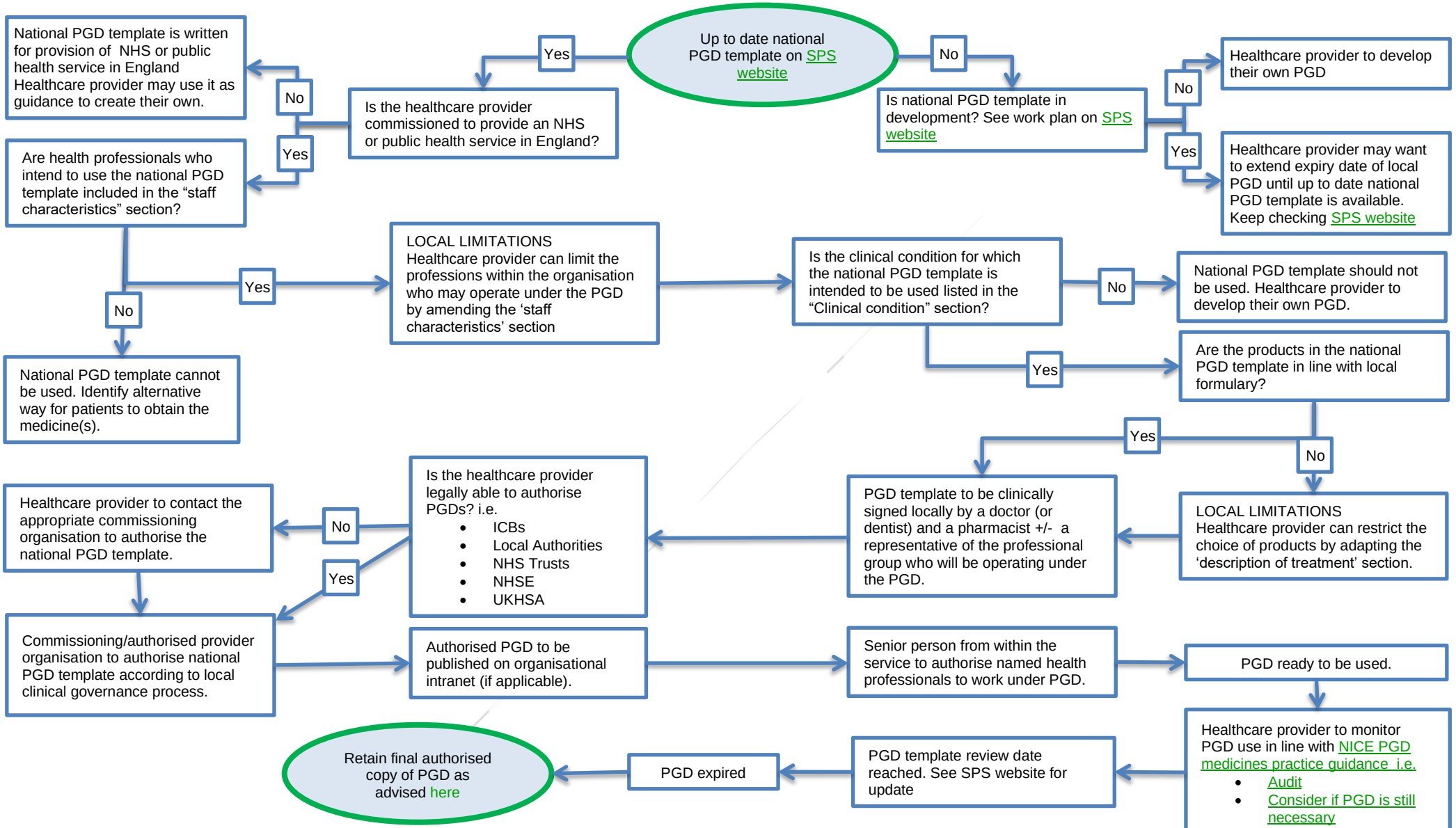
Further PGD guidance is available on the SPS website.

Any concerns regarding the content of this document or national PGDs should be addressed to: LNWH-tr.MUS-SpecialistPharmacyService@nhs.net

11. References

1. NICE Medicines Practice Guideline Patient Group Directions (2017) https://www.nice.org.uk/Guidance/MPG2 (accessed 28.10.19)
2. Lord Carter's review into unwarranted variations in mental health and community health services, NHSE 24 May 2018, https://www.england.nhs.uk/publication/lord-carters-review-into-unwarranted-variations-in-mental-health-and-community-health-services/ (accessed 28 October 2019)
3. The Human Medicines Regulations 2012, SCHEDULE16 Patient group directions http://www.legislation.gov.uk/uksi/2012/1916/schedule/16/made (accessed 28 October 2019)
4. Authorisation of Independent Healthcare Provider (IHP) PGDs for NHS and public health commissioned services, SPS 18 May 2017 https://www.sps.nhs.uk/articles/authorisation-of-independent-healthcare-provider-ihp-pgds-for-nhs-and-public-health-commissioned-services/ (accessed 28 October 2019)
5. Q&A Who are the PGD signatories? SPS, 11 May 2017 https://www.sps.nhs.uk/articles/who-are-the-pgd-signatories/ (accessed 28 October 2019)
6. Q&A What are the roles and responsibilities of the various signatories of patient group directions (PGDs)? SPS, 11 May 2017 https://www.sps.nhs.uk/articles/what-are-the-roles-and-responsibilities-of-the-various-signatories-of-patient-group-directions-pgds/ (accessed 28 October 2019)
7. Q&A Patient Group Directions in Complex Commissioning Scenarios SPS, 16 July 2018 (accessed 28 October 2019)
8. Retaining PGD documentation, SPS, 13 August 2018 https://www.sps.nhs.uk/articles/retaining-pgd-documentation/ (accessed 28 October 2019)

Appendix 1 - Flowchart for the authorisation & implementation of national PGDs templates



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