Specialist Pharmacy Service

NHS

Process for development, review and authorisation of national PGDs

The first stop for professional medicines advice

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Contents

1. Introduction

This document describes the process to develop, review and authorise national PGDs.

2. 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 May 2018 Lord Carter identified the duplication of effort across NHS organisations in producing PGDs.[2] The report recommended that NHS England's Specialist Pharmacy Service (SPS), overseen by the Regional Medicines Optimisation Committees (RMOCs), develop a national 'Do Once' system.

The Medicines Governance Do Once (MGDO) Secretariat consisting of members from SPS and NHS Improvement was established in 2018 to deliver the programme.

This document describes the process established by the MGDO Secretariat to develop, review and authorise national PGDs.

3. Decision to develop a new PGD

The MGDO Secretariat will determine the priority of developing new PGDs. This decision is multifactorial and will reflect national requirements. Generally PGDs will be developed where there is currently significant national usage, the treatment follows nationally available guidance and no other suitable mechanism for the supply and/or administration of medicines exists. The work programme is normally condition or pathway focussed which can result in more than one PGD being required for a medicine.

The MGDO Secretariat welcomes suggestions of new PGDs and will consider these as part of its prioritisation process.

Once a decision has been made to develop a PGD, a meeting of national stakeholders will be convened to ensure there is sufficient support for the work stream.

The MGDO Secretariat will use an assurance framework throughout the PGD development process to ensure all legal, clinical and governance requirements are met.

4. Development of a new PGD

Once the decision has been made to develop a new PGD, the MGDO Secretariat along with national stakeholders will decide on the appropriate subject matter experts (SMEs) to form a Short Life Working Group (SLWG). A lead doctor, pharmacist and representative(s) from the profession(s) working under the PGD will be appointed from within the SLWG; these members will become the core membership who will have responsibility for signing off the clinical content of the PGD.

[1] NICE Medicines Practice Guideline Patient Group Directions (2017) https://www.nice.org.uk/Guidance/MPG2 (accessed 29.11.18)
[2] Operational productivity unwarranted variations in mental health and community health services (2018). Lord Carter's review into unwarranted variations in mental health and community health services | NHS Improvement (accessed 29.11.18)

Following a call for examples of PGDs already in use in the care pathway or condition, the MGDO Secretariat will produce a first draft of a national PGD from the examples shared.

The draft PGD will be shared with the SLWG for comments. All comments will be collated by the MGDO Secretariat who will share these with the core members. The core members will discuss all the comments submitted and agree the changes to be made to the draft PGD. The changes will be made by the MGDO Secretariat. This second draft will be shared with the SLWG and comments will again be requested. These comments will again be collated by the MGDO Secretariat and shared with the core members. A second meeting of the core members will then take place and any further agreed changes will be made by the MGDO Secretariat. The aim is to arrive at consensus at this point, but where this is not possible, the SLWG will be informed and next steps agreed. The core members will have overriding decision on the clinical content as they will sign off the PGD.

The MGDO Secretariat will support the SLWG and core members throughout the process and will ensure the PGD assurance framework is met. Where this cannot be met the SLWG will be informed and will decide whether the PGD can proceed to ratification.

Where there are legal, regulatory or governance questions that cannot be answered by the MGDO Secretariat these will be referred to the PGD Service Advisory Board. The PGD Service Advisory Board has a remit to advise the national PGD Service.

Meetings may take place face to face but teleconferencing will be employed wherever possible.

The PGD clinical content will be signed off by the core members and the PGD will be locked so that no alterations can be made.

Where professional bodies have asked that they be included in this process the PGD will be submitted to them at this stage. Any issues raised at this stage will be reviewed by the core membership who will decide whether a further SLWG meeting is required to finalise the PGD.

The final PGD will then be submitted to the next RMOC meeting for ratification.

Following ratification the PGD will be made available on www.sps.nhs.uk and shared with other electronic portals as agreed within the work programme.

5. Review of a PGD

Where a PGD requires review because it is nearing its expiry date or because there have been major changes associated with the medicine or care pathway, then a SLWG will be convened. Members of the SLWG will be agreed following a consultation with national stakeholders.

The review process will follow that of the development process, but with the current PGD forming the basis of the draft version.

Minor amendments during the lifetime of a national PGD can be made with the agreement of the core member signatories and will be sent to the next RMOC for noting and then released via the SPS website.

Notification of all changes to national PGDs or the release of new PGDs will be made via the SPS news and/or Medicines Awareness Daily and via relevant professional bodies.

6. Authorisation of a PGD

To meet the requirements of the Human Medicines Regulations 2012 individual NHS trusts will need to locally authorise the PGD before it can be used in the organisation. Where an NHS commissioned service is provided by an organisation that is unable to legally authorise the PGD then the appropriate commissioner should be asked to authorise the PGD.[3]

7. Governance arrangements

All SLWGs and the MGDO Secretariat will have Terms of Reference. All members of the SLWGs and the MGDO Secretariat will complete annual declarations of interest. Any conflicts of interest will be recorded and if appropriate the member will be asked to stand down from the group.

The MGDO Secretariat is accountable to the RMOC who will approve all output prior to release.

The governance structure is shown in Figure 1

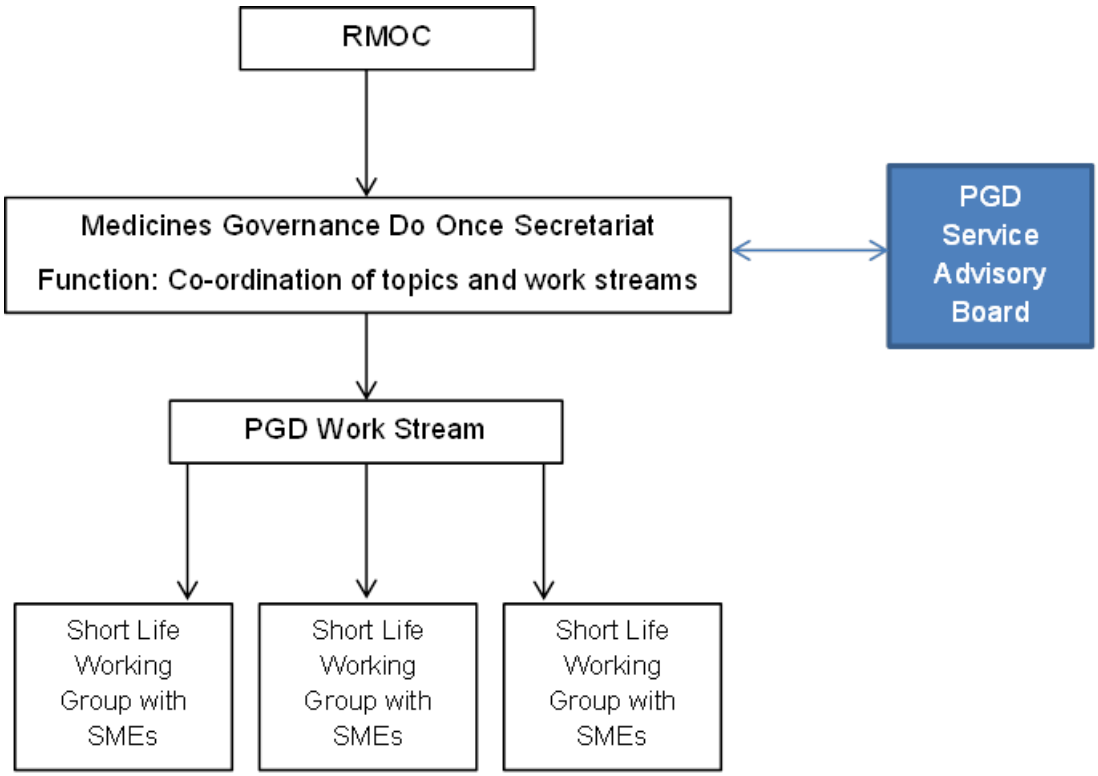

Figure 1: Governance Structure

[3] Authorisation of Independent Healthcare Provider (IHP) PGDs for NHS and public health commissioned services https://www.sps.nhs.uk/articles/authorisation-of-independent-healthcare-provider-ihp-pgds-for-nhs-and-public-health-commissioned-services/ (accessed 30.11.18)

8. Responsibilities

8.1 Responsibilities of the MGDO Secretariat

The MGDO Secretariat is responsible for delivering the programme. They will:

- abide by the Terms of Reference of the MGDO Secretariat
- complete a Declaration of Interest form at the start of the programme and annually thereafter
- liaise with relevant key stakeholders within the care pathway and invite subject matter experts (SMEs) to join the SLWG
- issue a call for examples of PGDs within the care pathway
- compile the first draft PGD
- collate responses from the SLWG and make changes as agreed by core members
- ensure the PGD assurance framework is met
- liaise with the PGD Service Advisory Board if required
- submit completed PGDs to the RMOC for ratification
- ensure PGDs are made available to organisations in a timely manner via agreed electronic portals.

8.2 Responsibilities of members of the Short Life Working Groups (SLWGs)

Members of the SLWG will:

- abide by the Terms of Reference of the SLWG.
- complete a Declaration of Interest form at the start of the SLWG and annually thereafter, if required.
- have the experience, knowledge, skills and expertise required to develop the PGD and be acknowledged as a subject matter expert (SME) within the clinical area.
- designate within the SLWG the core members as described in section 4
- adhere to agreed processes and procedures for the development, review and authorisation of national PGDs
- respond to requests for comments and information in a timely manner
- work towards consensus wherever possible.
- alert the MGDO Secretariat if early PGD review is required due to e.g. changes in best practice guidelines

8.3 Responsibilities of Core Members

In addition to those responsibilities listed in 8.2 core members will:

- discuss and agree which comments from the SLWG members should be included within the PGD
- take clinical responsibility for the content of the PGD
- sign the clinical content of the PGD acknowledging their responsibility in undertaking this task.[4]

8.4 Responsibilities of organisations using national PGDs

Organisations using national PGDs will:

- authorise them within their own organisation according to their clinical governance process.
- not change the clinical content within the PGD.

[4] What are the roles and responsibilities of the various signatories of patient group directions (PGDs)? (accessed 30.11.18)

- ensure staff working under the PGD are appropriately trained and competent.
- alert the MGDO Secretariat if early PGD review is required due to e.g. changes in best practice guidelines

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