Specialist Pharmacy Service

NHS

Process for development, review and publication of national SPS P/GSL medicine protocol templates

The first stop for professional medicines advice

Process for development and review and publication of SPS national P/GSL medicine protocol templates

Contents

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

1. Introduction

This document describes the process to develop, review and publish national P/GSL medicine protocol templates to support the supply/administration of these medicines.

2. Background

In May 2018 Lord Carter identified the duplication of effort across NHS organisations in producing Patient Group Directions and other governance documentation. The report recommended that NHS England's Specialist Pharmacy Service (SPS) develop a national 'Do Once' system[2] for the development of PGDs and other governance documentation.

The Medicines Governance Do Once (MGDO) Programme Board, and supporting Working Group were established in 2018 to deliver the programme.

PGDs are legally required for Prescription Only Medicines (POMs). However, Pharmacy Only (P) medicines can be legally administered, and General Sales List (GSL) medicines can be legally supplied or administered without a PGD, prescription or other legal authorisation. It is recommended that organisations have locally approved protocols in place to support the supply/administration of GSL/administration of P medicines.

As part of the MGDO programme where P or GSL medicines are identified as part of a workstream template national protocols will be developed.

This document describes the process to develop, review and publish national P/GSL medicine protocol templates.

3. Decision to develop a new SPS national protocol template

The SPS MGDO Programme Board will determine the priority of developing new national protocol templates. This decision is multifactorial and will reflect national requirements. Generally, protocol templates 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 Board welcomes suggestions of new protocols from NHS commissioners and providers and will consider these as part of its prioritisation process. The organisation proposing the new protocol(s) will be asked to submit a short paper to the Board detailing the rationale for development. This information will assist the Board in deciding whether the workstream is to be developed and, if so, the priority given to its development as part of the wider programme. The Board should consider the need for additional resource to provide the workstream and any additional funding required. Prioritisation which requires additional resource will need to be considered by the SPS Management Board before development can be agreed.

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

The Board, supported by the MGDO Working Group, will use an assurance framework throughout the protocol template development process to ensure all clinical and governance requirements are met. If required, the Board and the MGDO Working Group may seek advice from the SPS PGD Advisory Service Reference Group. The SPS PGD Advisory Service Reference Group has a remit to advise the national SPS PGD Advisory Service.

4. Development of a new SPS national protocol template

Once the decision has been made to develop a new national protocol template, the MGDO Working Group 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 protocol will be appointed from within the SLWG to form a core membership who will be the leads within the SLWG. Where relevant the relevant National Clinical Director or National Specialty Adviser will be informed of the SLWG and asked to contribute to the programme where relevant. Where available, the appropriate professional body/college who will review and endorse the template(s) will be agreed.

Following a call for examples of any protocols already in use in the care pathway or condition, the MGDO Working Group will produce a first draft of a national protocol template from the examples shared.

The draft protocol template will be shared with the SLWG for comments. All comments will be collated by the MGDO Working Group 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 protocol template. The changes will be made by the MGDO Working Group. This second draft will be shared with the SLWG and comments will again be requested. These comments will again be collated by the MGDO Working Group 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 Working Group. 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: where regulatory, governance or legal issues are identified advice will initially be sought from the Board and where required from the SPS PGD Advisory Service Reference Group noting that core members will have overriding decision on the clinical content of the final template.

The MGDO Working Group will support the SLWG and core members throughout the process and will ensure the protocol assurance framework is met. Where this cannot be met the SLWG will be informed and will decide whether the protocol template can proceed.

Virtual meetings will be employed wherever possible.

Once the content of the national protocol template has been agreed by the SLWG core membership the template will be submitted to the relevant professional body/bodies for approval (where available). 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 national protocol template. Where appropriate the relevant National Clinical Director or National Specialty Adviser will be asked to endorse the document(s).

The finalised national protocol template(s) and assurance checklist will be submitted to the Board, either at the next planned meeting or, where timescales dictate, by email agreement of Board members or at a specially convened meeting. The Board will provide independent assessment of assurance that the agreed development processes for the protocol template(s) have been followed.

Following this approval, the national protocol template 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 SPS national protocol template

Where a national protocol template requires review because it is nearing its expiry date or because there have been changes associated with the medicine, care pathway or supporting national guidance, 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 protocol template forming the basis of the draft version.

A rolling review of every protocol is undertaken by the SPS MGDO Working Group – this process involves continual review of all relevant SPCs and supporting national guidance. In life amendments required as a result of such changes which the SLWG deem cannot wait until the next scheduled review, can be made with the agreement of the SLWG core members.

Where the SLWG consider publication of the updated protocol template is urgent and cannot wait until the next Board, a request can be made to the MGDO Working Group to approve the updated protocol template for publication. Where requested, the MGDO Working Group will consider and, if appropriate, approve the publication of the updated national protocol template; an assurance checklist showing that all processes have been followed will be completed. If the working group decide that the changes need to be approved by the Board it will be referred to the next Board meeting or, where timescales dictate, by email agreement of Board members or at a specially convened meeting. A formal paper will be submitted to the next Board with details of the process undertaken, the assurance checklist and the names of the Subject Matter Experts involved.

6. Publishing and new or updated SPS national protocol template

All newly published national protocol templates will be highlighted via:

- email of the SPS weekly bulletin to the people registered on the SPS website;
- X (formerly known as Twitter) @NHS_SPS;
- LinkedIn (NHS Specialist Pharmacy Service);
- the Medicines Awareness Service bulletin

Similarly, notification of all changes to national protocol templates will be made via the same routes.

7. Local authorisation of a SPS national protocol

Protocols to support the supply/administration of GSL medicines or the administration of P medicines are not underpinned by legislation. Therefore, there are no legal requirements regarding their authorisation prior to use. However, the SPS MGDO Programme Board would advise organisations adopting the national protocol templates to ensure they are approved for use within organisations following a formal governance process which has been locally defined; it is anticipated that this process closely adheres to that followed for PGD authorisation.

SPS have published separate advice to support the process required for the local authorisation and implementation of the national PGD templates which organisation should refer to for further advice[4]. It provides a useful framework which organisations might wish to use when authorising a protocol.

8. Governance arrangements

All SLWGs and the MGDO Programme Board and MGDO Working Group have Terms of Reference. All members of the SLWGs, the MGDO Working Group and the MGDO Programme Board 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.

9. Responsibilities

9.1 Responsibilities of the MGDO Programme Board

The MGDO Programme Board is responsible for overseeing the programme. They will:

- abide by the Terms of Reference of the MGDO Programme Board
- complete a Declaration of Interest form at the start of the programme and annually thereafter

- oversee the programme of developing national protocol templates
- determine the priority of developing new national protocol templates
- support the MGDO Working Group as requested
- ensure the protocol assurance framework is met
- liaise with the SPS PGD Advisory Service Reference Group if required

9.2 Responsibilities of the MGDO Working Group

The MGDO Working Group is responsible for supporting the MGDO Programme Board in delivering the programme. They will:

- abide by the Terms of Reference of the MGDO Working Group
- 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 protocols within the care pathway
- compile the first draft of the national protocol template
- collate responses from the SLWG and make changes as agreed by core members
- ensure the protocol assurance framework is met
- liaise with the SPS PGD Advisory Service Reference Group if required
- submit completed protocol templates to the relevant professional body(s) for approval
- ensure national protocol templates are made available to organisations in a timely manner via agreed electronic portals.
- Undertake rolling review of all national protocol templates to ensure any required changes are highlighted to the SLWG members and made in a timely manner.

9.3 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 protocol template and be acknowledged nationally 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 and review of national protocol templates
- respond to requests for comments and information in a timely manner
- work towards consensus wherever possible.
- Alert the MGDO Working Group if early national protocol template review is required due to e.g. changes in best practice guidelines

9.4 Responsibilities of SLWG Core Members

In addition to those responsibilities listed in 9.3 core members will:

- discuss and agree which comments from the SLWG members should be included within the national protocol template

9.5 Responsibilities of organisations adopting national protocol templates

Organisations adopting national protocols will:

- authorise them within their own organisation according to their clinical governance process (see section 7).
- ensure staff working under the protocol are appropriately trained and competent.

SPS have published separate advice to support the process required for the local authorisation and implementation of the national PGD templates which organisation should refer to for further advice[4]. It provides a useful framework which organisations might wish to use when authorising a protocol.

10.References

1. NICE Medicines Practice Guideline Patient Group Directions (2017) https://www.nice.org.uk/Guidance/MPG2 (accessed 11/01/24) 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 11/01/24)
2. Authorisation of Independent Healthcare Provider (IHP) PGDs for NHS and public health commissioned services https://www.sps.nhs.uk/articles/authorising-independent-healthcare-provider-ihp-pgds/#:~:text=PGD%20IHP (accessed 13/03/2024)
3. Process for authorisation and implementation of SPS national Patient Group Direction (PGD) templates https://www.sps.nhs.uk/articles/implementing-the-national-patient-group-direction-pgd-templates/ (accessed 13/03/2024)

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