

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

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Approved by Medicines Governance Do Once (MGDO) Programme Board January 2023

# 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.

# 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’ system2 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 protocols will be developed.

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

# Decision to develop a new national protocol template

The MGDO Programme Board will determine the priority of developing new 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 MGDO Programme 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 Programme 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 Programme 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 Operational Group before development can be agreed.

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

The MGDO Programme 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 MGDO Programme Board and the MGDO Working Group may seek advice from the SPS PGD Service Advisory Board. The PGD Service Advisory Board has a remit to advise the national SPS PGD Advisory Service.

# Development of a new national protocol template

Once the decision has been made to develop a new 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. The relevant National Clinical Director or National Specialty Adviser will be informed of the SLWG and asked to contribute to the programme where relevant.

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 MGDO Programme Board and where required from the SPS PGD Service Advisory Board 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.

Meetings may take place face to face but tele/video conferencing will be employed wherever possible.

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

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

Following this approval, the protocol template will be made available on [www.sps.nhs.uk](http://www.sps.nhs.uk/) and shared with other electronic portals as agreed within the work programme.

1. **Review of a protocol template**

Where a 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.

In life amendments required as a result of changes to the supporting national guidance 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 Programme 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 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 Programme Board it will be referred to the next Programme 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 MGDO Programme Board with details of the process undertaken, the assurance checklist and the names of the Subject Matter Experts involved.

1. **Publishing and new or updated protocol template**

All newly published national protocol templates will be highlighted via the SPS news, SPS Twitter account (@SPS-NHS), SPS LinkedIn account and/or Medicines Awareness Daily and as well as via relevant professional bodies.

Notification of all changes to national protocol templates will be made via the SPS news, SPS Twitter account (@SPS-NHS), SPS LinkedIn account and Medicines Awareness Daily as well as via relevant professional bodies.

1. **Local authorisation of a 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 protocol 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 advice4.

# 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.

# Responsibilities

## 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 protocol templates
* support the MGDO Working Group as requested
* ensure the protocol assurance framework is met
* liaise with the SPS PGD Service Advisory Board if required

## 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 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 Service Advisory Board if required
* submit completed protocol templates to the relevant professional body(s) for approval
* ensure protocol templates are made available to organisations in a timely manner via agreed electronic portals.

## 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 protocol template review is required due to e.g. changes in best practice guidelines

## Responsibilities of 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 protocol template

## Responsibilities of organisations using national protocol templates

Organisations using 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.
* alert the MGDO Working Group if early protocol review is required due to e.g. changes in best practice guidelines.

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 advice4.

**References**

1 - NICE Medicines Practice Guideline Patient Group Directions (2017) <https://www.nice.org.uk/Guidance/MPG2>(accessed 24/09/20) 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](https://improvement.nhs.uk/about-us/corporate-publications/publications/lord-carters-review-unwarranted-variations-mental-health-and-community-health-services/) (accessed 24/09/20)

1. - 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/](https://www.sps.nhs.uk/articles/authorisation-of-independent-healthcare-provider-ihp-pgds-for-nhs-and-public-health-commissioned-services/) (accessed 24/09/20)
2. - Process for authorisation and implementation of SPS national Patient Group Direction (PGD) templates [https://www.sps.nhs.uk/wp- content/uploads/2019/02/Implementation-process-for-national-PGD-templates-V1-July-2020.pdf](https://www.sps.nhs.uk/wp-content/uploads/2019/02/Implementation-process-for-national-PGD-templates-V1-July-2020.pdf) (accessed 24/09/20)



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