Proposal to establish and oversee a national ‘do once’ system for organisational medicines governance

1. Introduction

The purpose of this paper is to outline how Lord Carter’s recommendation, in his recent review of mental health and community health services (1), that ‘NHS England’s Specialist Pharmacy Service and the regional medicines optimisation committees develop a national ‘do once’ system for organisational medicines governance, including national standardised medicines policies, patient group directions and other essential organisational governance documents during 2018/19’ can be implemented, and to provide timeframes and priorities.

The request is for the Regional Medicines Optimisation Committee system across England to

• endorse the development of a suite of medicines governance documents (patient group directions and medicines policies).
• provide oversight for the national programme of work to develop / produce these documents.
• note availability of published outputs, endorse the implementation of these documents as a single source and ensure integration into other relevant work programmes eg antimicrobial resistance.

2. Background

The first Carter Review, published in February 2016, set out a vision with recommendations for improving both productivity and efficiency within the NHS (2). This Review highlighted where unwarranted variation exists within the NHS and tasks organisations to examine themselves against agreed benchmarking metrics. Specifically for pharmacy the report suggested that organisations should ensure that their pharmacists and clinical pharmacy technicians spend more time on patient-facing medicines optimisation activities. This is essential to deliver the Medicines Value Program (3), enabling pharmacy teams to increase provision of clinical medication reviews and patient-centred medicines support.

In 2018, the SPS undertook an exercise to determine the numbers and range of Patient Group Directions (PGDs) for antimicrobial therapy in use in a sample of NHS providers. This revealed a significant duplication of effort at local level. It also revealed wide variation in the quality of PGDs, standards of implementation (such as keeping adequate registers and undertaking audits) and training provided to healthcare professionals who use PGDs (4). Across 18 Trusts there were 199 PGDs for provision of antimicrobial therapy, by removing duplication this could be reduced to 33.

Lord Carter also identified duplication of effort in his most recent report (May 2018) for both PGDs and medicines policies (1). There is an opportunity to improve NHS productivity by standardising the development of PGDs, medicines policies and other essential organisational medicines governance documents. A ‘do once’ approach to develop quality assured PGDs and essential medicines governance documents which are adopted locally is being proposed. This will release significant local resource to be redeployed on optimising outcomes from medicines use.

There is evidence from a previous pan-London initiative that standardising PGD templates provides a consistent and high standard of care no matter where a patient presents (5) and Public Health England (PHE) already publish a range of national PGDs for immunisation in primary care (6).
The Regional Medicines Optimisation Committees (RMOCs) provide a single strategic medicines optimisation system for England. The Committees’ remit includes support for national initiatives relating to medicines and productivity improvement through reduced local duplication. The RMOCs provide the necessary infrastructure to enable and implement this work programme on national medicines governance documents (7).

3. Scope

- PGDs, medicines policies and other medicines-related organisational governance documents for NHS commissioned services and other publicly funded commissioned services (e.g. by Local Authorities) in England

3.1 Patient Group Directions

A number of short life working groups (SLWGs) will be convened over the course of the three year programme. These will bring together subject matter experts (SMEs) from a range of disciplines who will undertake the review and consolidation of existing PGDs. These groups will ensure the safety and clinical accuracy of proposed national PGDs. PGDs will then be submitted to the Medicines Governance Do Once (MGDO) Secretariat for scrutiny to ensure compliance with legislation before onward submission for ratification by the RMOC (see Section 5 Governance).

The MGDO Secretariat will prioritise those areas where there is significant commonality to achieve the greatest reduction in repetition of work across the health economy. This will also deliver improvements in quality and consistency of patient care.

PGDs will be designed to be suitable for local adoption by all providers. It is the expectation that no local amendment will be required. This reflects the current PGD process developed by PHE to support the national immunisation schedule. In common with the PHE templates, local organisational authorisation of the PGDs will still be needed. This is a legal requirement (Human Medicines Regulation 2012) (8).

It is anticipated that the process will reveal areas where PGDs are being used unnecessarily. Recommendations will be developed to support organisations implement more appropriate processes.

3.2 Medicines Policies

Building on the first year of the programme, a review of existing medicines related policies will be undertaken to enable prioritisation of the work programme.

This aim will be to improve the quality and consistency of documentation, and reduce duplication of effort. Examples may include medicines policies, controlled drug policies and others.
4. Timescale

It is anticipated that this will initially be a 3 year delivery programme. The proposed timeline and programme deliverables are given below.

<table>
<thead>
<tr>
<th>WorkStreams</th>
<th>Programme Deliverables</th>
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<tbody>
<tr>
<td><strong>Year 1 2018/19</strong></td>
<td><strong>PGDs</strong></td>
</tr>
<tr>
<td></td>
<td>• Scoping exercise of scale of current situation with PGDs and agree priorities</td>
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<td>• Establish a national process to review consolidate and update</td>
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<td></td>
<td>• Reduce the number of PGDs e.g. those being used for General Sales List medicines and medicines in HMR2012 Schedule 19</td>
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<td>• Work with NHSI &amp; PHE to develop the first national antibiotic PGDs through the establishment of a SLWG</td>
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<td>• Work with the 10 Ambulance Trusts in England to support the development of national set of PGDs for ambulance services via SLWGs set up with Ambulance Trusts.</td>
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<td><strong>Year 2 2019/20</strong></td>
<td><strong>PGDs</strong></td>
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<td></td>
<td>• Build on the learning from 18/19</td>
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<td></td>
<td>• Scope and develop PGDs for contraceptive and sexual health services.</td>
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<td></td>
<td>• Continue to develop PGD work stream. Establish a further number of SLWG dependent on capacity</td>
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<td></td>
<td><strong>Policies</strong></td>
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<tr>
<td></td>
<td>• Establish a national process</td>
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<td></td>
<td>• Scope the potential for national templates for NHS provider medicines policies</td>
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<tr>
<td><strong>Year 3 2020/21</strong></td>
<td><strong>PGDs</strong></td>
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<td></td>
<td>• Continue to develop contraceptive and sexual health services PGD template workstream.</td>
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<td></td>
<td>• Scope other clinical areas for PGD development.</td>
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<td>• Maintain, review and update released PGDs according to review dates or changes in clinical guidance/product characteristics etc.</td>
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<td></td>
<td>• Establish a process to review consolidate and update</td>
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<td></td>
<td><strong>Policies</strong></td>
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<tr>
<td></td>
<td>• Build on learning from 19/20</td>
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<td>• Continue to develop national templates for provider medicines policies.</td>
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5. Governance

The proposed governance structure is shown in Figure 1.

The current PGD Service Board will continue to provide advice to the MGDO Secretariat. The current terms of reference of the PGD Service Board are in Appendix 1.
The MGDO Secretariat will be established to oversee this proposal and prepare papers for the RMOC. (MGDO Secretariat Terms of Reference see Appendix 2.)

- The MGDO Secretariat will sit under the RMOC who will ultimately ratify the work of the MGDO Secretariat including publication and sharing with the NHS and partners.

- The MGDO Secretariat will be provided by SPS who will co-opt nationally acknowledged SMEs. The MGDO Secretariat will work with the SMEs in short life working groups to develop the PGDs and medicine policy templates, leading the consultation and submission for the authorisation processes.

- The MGDO Secretariat will be supported by the PGD Service Board which consists of key stakeholders including CQC, MHRA, PHE, NICE, DHSC, NHSE, SPS, providers from all sectors, multidisciplinary representation. The MGDO Secretariat will hold overall responsibility for the programme.

Figure 1 Governance Structure
Stakeholders

As medicine policies and PGDs require continuous multidisciplinary engagement it is essential that a wide range of key stakeholders are involved. Table 1 shows the range of stakeholders that have been initially identified, but it is acknowledged that this will increase as the programme matures.

Table 1: Stakeholders

<table>
<thead>
<tr>
<th>Group</th>
<th>Stakeholders</th>
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<tbody>
<tr>
<td>Professionals</td>
<td>Nurses, Doctors, Pharmacists, Allied Healthcare Professionals (AHPs), Service managers, leaders, directors</td>
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<tr>
<td>Provider organisations</td>
<td>NHS Acute, Ambulance, Community and Mental Health Trusts, General Practitioners (GPs), Clinical Commissioning Groups (CCGs), Community Pharmacies, Prisons and Secure Environment Healthcare Services, Independent Healthcare Providers (providing NHS commissioned services), Care Homes</td>
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<tr>
<td>National expert partners</td>
<td>Royal Colleges, Professional Bodies, NICE, MHRA, CQC, PHE</td>
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<tr>
<td>Patients and carers</td>
<td>Via RMOC Patient Members</td>
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References


4. Use of Patient Group Directions for the supply and administration of antimicrobial agents SPS – https://www.sps.nhs.uk/


Appendix 1 PATIENT GROUP DIRECTIONS (PGD) SERVICE BOARD TERMS OF REFERENCE 2018

As at November 2017, SPS PGD Board membership is as follows:

Regulatory, Policy and Guidance
- Department of Health (DH): Non-medical Prescribing Medicines Pharmacy and Industry
- Care Quality Commission (CQC): Member of Medicines Optimisation Team
- Medicines and Healthcare Products Regulatory Agency (MHRA) – Senior Policy Manager
- NHS England Allied Healthcare Professions Medicines Project Lead
- NHS England Deputy Chief Allied Health Professions Officer
- NHS England Deputy Chief Pharmaceutical Officer
- NICE - Associate Director – Medicines Evidence and Advice, Medicines and Technologies Programme
- Public Health England – Lead Pharmacist Immunisation Services

Professional Advisors
- Nursing – Independent Nurse Consultant
- Nursing – NHS Trust/Medicines Management Nursing Network representative
- NHS England Specialist Pharmacy Services (SPS)- Medicines Use and Safety Division - Director
- NHS England Specialist Pharmacy Services (SPS)- Medicines Use and Safety Division Primary and Community Care – Associate Director
- NHS England Specialist Pharmacy Services (SPS)- Medicines Information Director London and South East England Region
- NHS England Specialist Pharmacy Services (SPS)- Specialist Lead Pharmacist PGDs
- Acute/Secondary Care Pharmacy – three pharmacist members
- CCG Lead Pharmacist
- Local authority Pharmacist
- Independent healthcare provider representative– one pharmacist member

Trade bodies
- National Pharmacy Association Head of Pharmacy (representing independent community pharmacy contractors only)

Membership review
To allow for organisational changes and potential new stakeholders for the website, membership will be reviewed and updated each year or earlier if necessary.

PGD BOARD CHAIRPERSON

The Chairperson of the PGD Board will be elected by Board members for a period of three years. If the incumbent Chairperson wishes to continue in the role after their three year tenure this is permissible with the support of the PGD Board and there is no maximum period of repeat tenure.

If the Chairperson is unable to attend the annual PGD Board meeting they will nominate a Deputy Chairperson prior to the meeting.

ANNUAL PGD BOARD MEETING

The Board will meet on an annual basis, in November, to review progress, discuss issues around PGDs in practice.
and influence the development of content. Meetings will be arranged to support attendance by tele or video conferencing if requested by Board members.
Advice and support between board meetings is handled through correspondence and telephone calls.

Board membership requires each Board member (or a named deputy) to attend, in person or by teleconference, the annual Board meeting. If attendance at a Board meeting is not possible, the Board member is expected to contact the Specialist Lead Pharmacist PGDs prior to the meeting to discuss current PGD issues.

The meeting will be quorate if following are in attendance:
- Chairperson (or nominated deputy)
- Representative from the Care Quality Commission (CQC)
- Representative from the Medicines and Healthcare Products Regulatory Agency (MHRA)
- Representative from the Department of Health (DH)
- Representative from the National Institute for Health and Care Excellence (NICE)
- Representative from the Specialist Pharmacy Service (SPS)
- A minimum of one pharmacist
- A minimum of one clinician

RESPONSIBILITIES OF BOARD MEMBERS

The PGD Board is a source of expert opinion to oversee the development and maintenance of the SPS PGD service and to ensure it meets the needs of stakeholders at a strategic level. The Specialist Lead Pharmacist (PGDs) periodically needs to access this expert opinion to ensure that the content is reliable, robust and relevant.

Board members (with the exception of observers) are also required to help respond to complex enquiries about PGDs. Support is also required to help provide an interpretation of Regulations and for responses to some consultations.

Board membership requires each Board member to respond to emails and documents sent out for consultation within a stated timeframe. If no response is received within the timeframe given, it will be assumed that the Board member has no comment and is satisfied with the content, unless this is a regulatory or policy matter when the Board member(s) will be contacted to discuss any reasons for delay and a process to resolve any remaining issues is agreed.

Minimum activity level for Board members is to attend the annual Board meeting (or as outlined above) plus respond to at least two consultations per year (acceptable responses include ‘no comment/satisfied with changes’).

Where a Board member does not fulfil these criteria, the Board will agree any suggested withdrawal of membership before Board membership is withdrawn.

If any Board member has an extended period of absence their nominated deputy will be contacted if required for advice or comment on consultations.

When a Board member leaves their role, either their successor will be invited to join the Board or Board members will be invited to nominate a suitable replacement candidate or to agree to retain the Board member in their new role.

COMMUNICATION

Evidence received via the PGD service that highlights problems professionals or users may have, for example in relation to current legislation or gaps in services, will be brought to the Board’s attention.

SPS CL August 2018
Board members will be expected to relay any communication via their networks where relevant with reference to any communication about new or updated content on the website.

The Board will identify any new strategic stakeholders so that the Specialist Lead Pharmacist PGDs can ensure channels of communication are developed and/or maintained.

QUALITY ASSURANCE AND PERFORMANCE MANAGEMENT

All activity for the SPS PGD Service is supported by a Process and Methods Manual and Standard Operating Procedures.

The Specialist Lead Pharmacist PGDs will produce periodic updates to assure the Board that the aims of the site and the agreed objectives are being met.

One report per year will be produced and will be circulated with the agenda for the annual Board meeting, which will normally take place in the month of November.

The annual Board meeting will act as a forum to review performance of the website and ratify that associated information on the website is up to date and fit for purpose.

This will be used by NICE as part of an overall performance matrix for the website.

NICE contributes resources to the support the contractual management of the service, including scheduling quarterly contract management meetings and providing the annual Service Level Agreement Standards and Key Performance and Quality Indicators template.
### Title
Specialist Pharmacy Service Medicines Governance Do Once Secretariat

### Objectives of the Group
- To lead on and oversee the development, ratification and release of:
  - national Patient Group Directions (PGDs) for adoption within NHS organisations and other publically funded commissioned services based on priorities determined by the national agenda.
  - templates for medicines related policies for adaptation and adoption within NHS organisations and other publically funded commissioned services.

### Remit
The Secretariat will:
- Develop and agree a workplan and workstreams for national PGDs and medicines related policies development.
- Prioritise the agreed workplan and workstreams.
- Establish and oversee Short Life Working Groups (SLWGs) for each identified workstream. (Note it is the SLWGs who will be responsible for drafting and finalising PGD templates/medicine related policies within the timescales set out in the workplan.)
- To liaise with the PGD Service Board to seek clinical, operational and legislative clarity on national PGDs as required.
- Receive and scrutinise the finalised PGDs/ medicines related policies from the SLWGs to ensure legislative and process requirements are met. If required respond to the SLWG Chair with any queries or areas for further development.
- Submit the finalised national PGDs/medicines related policies to the RMOC for ratification. Respond to any requests for further information from the RMOC.
- Upload the final national PGDs/medicines related policies to the SPS website and communicate to all NHS and other relevant publically funded commissioned services which PGDs/policies have been released.
- Maintain the workplan and advise the SLWGs when a PGD/policy is due for review and re ratification. In cases of a change in national guidance or a change to the licensing information for a medication included in a national PGD/policy during its valid life, the Secretariat will alert the Chair of the relevant SLWG and request that the PGD/policy be reviewed accordingly.
- Consult with services and stakeholders who express an interest in...
providing feedback and comments concerning the work plan or work streams.

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<thead>
<tr>
<th>Membership</th>
<th>The group will consist of the following:</th>
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<tbody>
<tr>
<td></td>
<td>• Secretariat Chair (Head of SPS)</td>
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<td>• Medicines &amp; Pharmacy Professional Advisor, NHS Improvement</td>
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<td></td>
<td>• Director, SPS Medicines Use and Safety (Deputy Chair)</td>
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<td></td>
<td>• Associate Director SPS (two members)</td>
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<td></td>
<td>• SPS Specialist Pharmacist PGDs</td>
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<td></td>
<td>• Additional members/specialist reviewers as identified for subsequent resource development</td>
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| Frequency of meetings | • The Secretariat will meet every 3 months – meetings will be planned alongside the RMOC schedule to ensure efficiency in submitting documents for ratification. |
|                      | • Regular contact and updates in work plan (including circulation of all meeting papers and drafts/finalised documents for comment/review) will be undertaken electronically. |
|                      | • Final PGD/policy documents can be agreed for submission to the RMOC for ratification via email agreement or via teleconference at the discretion of the Secretariat Chair. |

| Attendance at meetings | • All arranged meetings will be attended by members unless agreed otherwise with the Chair. If a member is unable to attend a meeting they will provide written comments to any papers within an agreed timeframe. |
|                       | • All electronic correspondence should be responded to within the agreed timeframe stated on all correspondence requiring a response. If no response is received within the time frame it will be assumed that the member approves the content and has no comment to make. |

| Duties and responsibilities | • Members are expected to attend all arranged meetings or provide written input if unable to attend. |
|                            | • Members are expected to review outputs according to an agreed plan and process and to do so in a timely manner. |

| Accountability | • This work is being carried out with the agreement of NHS England and NHS Improvement and is led by the Specialist Pharmacy Service (SPS). |
- The members of the Secretariat are accountable to their own professional bodies for their input and conduct.

**Governance**

- The Secretariat is accountable to the RMOC for the submission of documents for ratification in line with the workplan.
- Work of the Secretariat is supported NICE Medicines Practice Guidelines 2 PGDs and national guidance relevant to each identified workstream.

**Confidentiality**

Secretariat activity is to be treated as confidential within the group unless there has been prior agreement with the Chair to share outputs or to consult with named, agreed stakeholders.

**Declaration of interest.**

Members must complete a Declaration of Interest Form for each calendar year and declare relevant interests, stating whether their interests are specific to a product or a pharmaceutical company under consideration.

Any new interests which arise must also be declared.

The Chair will consult with the group to agree whether a member who declares a relevant interest in a specific product or products could continue to work with the group for a particular piece of work or for the whole part.

**Terms of Reference**

Members will agree to and abide by these Terms of Reference.