



The NHS Specialist Pharmacy Service

National Service Specification (April 2022 to March 2025)

The first stop for professional medicines advice





1 Purpose

This document outlines the strategic intent for the NHS England & Improvement (NHSEI) commissioned Specialist Pharmacy Service (SPS). It specifies the key areas for delivery by the service. The functional groups (medicines information, medicines use & safety, quality assurance and procurement) will work collaboratively to achieve these deliverables.

This document forms the national specification for the SPS in England and aims to provide clarity to both the service users and SPS providers on access, levels of service and performance. It provides bidders with the detailed specification for the elements of the service which are being tendered.

Any local activities and requirements delivered at a sub-regional level, which fall outside of this specification, will require local decisions to be made on future delivery and funding.

2 Overarching Service Structure and Function

The NHS Specialist Pharmacy Service (SPS) supports the NHS to develop best practice systems of work related to buying, making and using medicines. The service provides leadership, instructive and informative specialist input and operational support to the sourcing, supply and use of medicines across the system. The NHS SPS's strengths are borne out of connecting national expertise with policy teams and arm's length bodies to ensure consistency and high standards. The service supports both regional and local connections to ensure that the service's outputs resonate with and support local NHS organisations which deliver care to patients. The key successes of SPS are through the development and delivery of their "Do Once and Share" methodology.

The service has been in existence regionally since the 1970s and in its current form since 2013. The purpose of the NHS SPS remains the same as it was in its original iteration which is to deliver specific pharmacy and medicines related functions in the most cost effective and efficient way. This is at a level higher than a single hospital. Over the years, this has enabled senior expertise to be retained, focussed, and shared, in a way which is not possible or affordable if individual organisations were required to do the same thing locally.

2.1 Service Structure

The service specification has been written to align to an overarching strategic function. The primary purpose of the SPS being to provide end to end support for the supply and use of medicines by the NHS in delivering care to patients. The revised service structure will deliver greater strategic leadership through enhanced governance and oversight by a single commissioner. The alignment of the SPS specialist functions also fosters resilience, removes duplication, and ensures that the service is both efficient and cost effective in its delivery. The revised structure will provide the SPS with a strengthened presence by providing

- a. A consolidated management structure with personnel appointed to lead the functional hubs and aligned to national committee for that function.
- b. A "do once and share" approach and workplan delivered through the hub and spoke model.
- c. Specific support to NHSEI's Systemisation of Medicines Optimisation work programme through enhanced support to the Regional Medicines Optimisation Committee (RMOC) network.
- d. A robust, bespoke digital infrastructure to support delivery to a geographically dispersed, multidisciplinary professional audience
- e. Identified project management office support throughout the service.





- f. A clear career pathway with succession planning built into the service by the introduction of rotational SPS posts across a series of bands 8a to 8c which are aligned to specific gateways in terms of development.
- g. Contribution of specialist subject matter expertise to inform local and national initiatives to develop the specialist pharmacy workforce.

The Head of SPS will have clear line of sight of SPS-employed individuals, with the service formally managed through service contracts and personnel management, appraisal, and objective setting.

All will be expected to work to a single operational model commissioned against NHSEI priorities, with the same governance and standard operating policies and procedures which ensure equity of delivery and of access to all SPS functions by the target audience. Across a regional footprint, it is expected that SPS functions will foster a working relationship with their Regional Chief Pharmacist and that there will be a designated place on the Regional Pharmacy Leadership Board or equivalent for a SPS representative(s).

2.2 Service Specification

The NHS Specialist Pharmacy Service (SPS) covers a range of services which provide invaluable support to NHS services across all sectors of the NHS and encompass the following elements:

Medicines Procurement and supply: the provision of strategic advice to policy makers and implementation support for the procurement of medicines for hospitals providing NHS services

Pharmaceutical Quality Assurance: a range of activities relating to the audit of medicines preparation, standards, conduct of clinical trials, advice and assessment of medicines for procurement.

Medicines Information: the specialist information and advice for health care professionals, patients, public and policy makers on medicines use

Medicines Use and Safety: enabling commissioners and providers to implement national priorities and local initiatives to improve patient safety.

Put simply SPS supports the NHS to develop best practice systems of work related to buying, making and using medicines, "BUY THEM, MAKE THEM, USE THEM". It provides leadership, education and operational support to the sourcing, supply and use of medicines across the system.

Within each of the functions of buying, making and using medicines SPS, as a NHS Medicines Service, will

- a. Provide information and advice about medicines
- b. Review and audit practice, promoting good practice through standardisation
- c. Develop "do once and share" systems and processes of work
- d. Deliver instructive and informative input via SPS's subject matter experts in order to support the pharmacy workforce and its networks
- e. Support innovation and continuous quality improvement.
- f. Provide expert subject matter advice when required to support any aspect of the manufacture, procurement, supply or safe use of medicines

Individual work programmes will be agreed by the SPS management board and an annual workplan published on the SPS website. The SPS Management Structure and the detailed service function specifications may be found on the following pages.



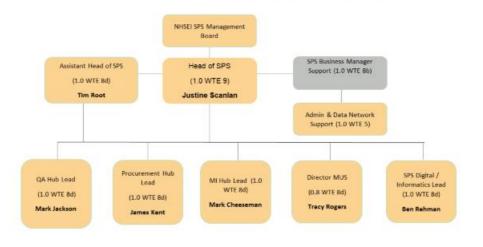


Figure 1: SPS Management Structure





STRUCTURE: MANAGEMENT



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SPS Medicines Use and Safety (MUS) Function

The SPS Medicines Use and Safety function supports the safe use of medicines across the NHS by providing resources and outputs that prevent duplication, and by developing and facilitating professional networks.

Programme 1: Medicines Governance Do Once (MGDO)

The MGDO Programme will develop national Patient Group Direction (PGD) templates and resources on medicines policy and governance principles for the NHS. Nationally credible internal and external Subject Matter Experts (SMEs) will support this do once approach.

Oversight of the work plan will be provided by the MGDO Programme Board.

SPS MUS will:

- develop template PGDs according to the determined work plan for medicines in common care pathways.
- maintain all PGD templates within their expiry as new evidence, guidance and policy becomes available. Current areas in the work plan: reproductive and sexual health services, imaging services, preventative medicines in pregnancy, ambulance services, out-of-hospital care.
- provide subject matter expertise on the governance, legislation and implementation of PGDs.
- publish resources to address common and emerging issues associated with PGDs.
- provide an expert PGD enquiry answering service.
- develop resources to support medicines policy and governance principles, with the aim of enabling the dissemination of key points for local consideration.

Programme 2: Medication Safety and Optimisation (MSOP)

The MSOP programme will support the implementation of the national medicines safety agenda and will be aligned with the Medication Safety Improvement Programme and the NHSEI safety agenda. It will provide leadership across the SPS Functions for all matters relating to patient safety.

SPS MUS will:

- support the development and implementation of national medicines safety alerts, evaluate the risks associated with medicines in use, and provide resources to the NHS to spread and embed good practice.
- lead and co-ordinate the national monthly webinars for Medication Safety Officers (MSOs) to share best practice, reduce duplication of effort and collectively consider new and emerging risks.
- link into the regional MSO networks and act as a conduit for medication safety information between the different levels within the system.
- produce support materials that enable both newly designated and established MSOs to fulfil their role effectively.
- develop and publish a range of resources to support medicines optimisation across the system that improve medicines safety practice





Programme 3: Medicines Network Leadership

SPS MUS will support all practitioners to provide better medicines optimisation by leading and delivering several networks. Best practice in the use of medicines will be identified by consensus and shared nationally, utilising the skills and knowledge of consultant and specialist pharmacists. This workstream will be aligned to NHSEI priorities.

SPS MUS will:

- co-ordinate a range of professional pharmacy networks through webinars and events to share best practice in clinical settings and clinical pathways.
- embed new developments in the SPS offer to reflect system transformation.
- expand the repertoire of outputs in line with end user content consumption.





SPS Medicines Information (MI) Function

The SPS MI function provides specialist information and advice about medicines use for health care professionals, the public and policy makers. There are 3 core service elements to the MI function:

- 1. Clinical Enquiry Answering
- 2. Provision of Information and Resources
- 3. Support to the Regional Medicines Optimisation Committee Network

1. Clinical Enquiry answering for professional audiences

The SPS MI function will provide evidence-informed clinical advice about the safe and effective use of medicines to a broad range of healthcare professionals caring for NHS patients across England.

This function will be delivered with national oversight and utilise a digital solution to maximise efficiency and local self-sufficiency. This arrangement will ensure consistent, efficient, and timely service delivery and minimise variation.

The SPS MI function will assist health-care professionals in their management of NHS patients with complex medicines problems to ensure treatment is safe and effective. This service will be delivered through the provision of evidence-based information and advice to the following service users

- Pharmacy and other healthcare professionals including GPs and practice nurses caring for patients in primary and community care settings to include care homes
- Those who commission services on behalf of the NHS

Users will access the service via a single point of contact using a range of communication routes to meet the needs of service users. Hours of operation, i.e. responses received and provided, will initially be from 0900 to 1700 Monday to Friday.

Regular analysis of clinical enquiry data will be undertaken to determine commonly asked or complex questions, or themes about medicines. The result of this analysis will be used to inform SPS outputs published via the SPS website (see Information and resources)

Services and Enquiries outside scope:

- Formulary evaluations and medicine pathway redesign
- Preparing an Individual Funding Request
- Writing a clinical guideline
- Writing a Patient Group Direction (see MUS function)
- Acute poisoning/overdose
- · Support for individuals conducting own research
- Delivery of a routine clinical enquiry answering service to individual acute hospitals, mental health or community health service Trusts.

2. Provision of Information and Resources

SPS MI will maintain and develop a suite of "do once and share" resources which will support the safe and appropriate use of medicines in the NHS. The aim of this programme is to ensure that information and resources are delivered to the NHS using an agile approach that ensures quality and usability and that content is maintained so it continues to deliver to end user requirements.

The scope will include the following broad themes:





- Resources to support the managed entry of new medicines into the NHS e.g. horizon scanning resources, patent expiry information, genomics, patient safety.
- Resources to support clinical medicines optimisation and patient safety e.g. drug monitoring, supply chain management/shortages (also see Procurement & QA functions), medicines awareness daily service on behalf of NICE, omitted and delayed doses, loading doses
- Resources to help healthcare professionals ensure safe and effective use of medicines in specialist populations e.g. breastfeeding or pregnant women.
- Resources to support pharmaceutical medicines optimisation e.g. temperature deviation, oral medicine stability, high risk injectable medicines
- Providing information in response to requests made by NHSEI and the Department of Health and Social Care (DHSC) to support priority programmes and required as a consequence of policy decisions and medicines supply issues.
- Reacting to new and emerging issues as they arise across the health system, e.g. resources to support the COVID-19 pandemic utilising wider SPS skills and expertise.
- Support to workforce development by providing instructive and informative subject matter expertise to support training events.

For each SPS published resource the following will be considered:

- Process for identification of potential content e.g. questions raised via:
 - o clinical enquiry service,
 - o SPS webinars, website, operational board,
 - o user engagement,
 - o national meetings and professional networks
 - o NHSE, DHSC
- Definition of user need and through engagement (as appropriate)
- Identification of partners/stakeholders internally and externally to SPS including membership/representation at national working groups/committees
- Prioritisation
- Governance of all content including externally authored resources e.g. Medicines awareness daily published via NICE, social media (SPS Twitter),
- Alignment with SPS digital strategy (see digital function) and adherence to usability standards and principles
- Ongoing maintenance of resource to ensure continuing currency and relevance acting upon business intelligence to achieve this.

3. Regional Medicines Optimisation Committees

The MI function will support the delivery of seven NHSEI Regional Medicines Optimisation Committees (RMOC) and one Medicines Optimisation Delivery Group (MODG). The RMOCs have been charged with





providing the strategic medicines optimisation link between national/regional priorities and local system implementation (i.e. ICSs). The MODG is responsible for co-ordinating activities of the RMOC.

SPS will support delivery of the RMOCs through the following activities:

Secretariat support

- Provision of the secretariat/professional support function to the RMOCs in England for up to 42 meetings per year. This will be delivered in accordance with the Operating Model (October 2021) and will be facilitated through a dedicated RMOC web presence on the NHS Futures website:
 - o Co-ordinate agenda, decisions and actions
 - o Ensure governance processes are adhered to
 - o Ensure that the RMOC works within the Operating Model (e.g. in terms of committee membership)
- Provision of secretariat/support function to the Medicines Optimisation Delivery Group (MODG) for up to 4 meetings per year.

Professional support

- Support MODG with oversight of the RMOC workplans in order to reduce duplication of effort. Coordinate reporting of RMOC activity to the MODG.
- Support the Regional Chief Pharmacist and Regional Medical Director to manage the work-programme for the RMOCs in England in line with the Operating Model (October 2021).
- Communicate with RMOC stakeholders via routes described in Operating Model (October 2021) to support implementation of actions recommended by the RMOCs.
- Maintain a communication list and co-ordinate the communication of RMOC outputs to Integrated Care System Chief Pharmacists.
- Co-ordinate the actions of the RMOC system to ensure a consistent and coherent delivery of RMOC outputs for the NHS in England.

Outside scope:

- Support for subgroups and Short Life Working Group
- Data analysis, data monitoring and collation of metrics/dashboards
- Projects/pieces of work identified as an action from the RMOCs or MODG





SPS Procurement Function

The SPS Procurement Function will facilitate access to the most appropriate medicines for NHS organisations and patients delivered via a robust supply chain. Input may be required at any point of the supply chain from access to active pharmaceutical ingredient (API) through to delivery of medicinal products to patients. Support will be delivered via a range of coordinated activities across the system at a national, regional and local level.

1. National Medicine Optimisation and Contracting Work Programmes

The SPS Procurement function will provide specialist pharmacy advice to the Commercial Medicines Unit (CMU) as part of their national medicines tendering and contracting remit. This will include

- a. Delivery of the Pharmaceutical Market Support Group (PMSG) work programme, as directed by the National Pharmaceutical Supplies Group (NPSG). NOTE: NPSG/PMSG are CMU committees. CMU provides the link to the Medicines Value Programme and Commercial Medicines Team.
- b. Attending and contributing to key groups & networks to include the following
 - National Pharmaceutical Supplies Group (NPSG),
 - The Pharmaceutical Market Support Group (PMSG) and associated subgroups (Generics, Branded and Biosimilars, National Homecare Medicine Committee, National Patent Group) with the following aims
 - **Generics:** To provide specialist support & advice to guide national procurement of generic medicines. This should include input into how to maintain the plurality and sustainability of the market.
 - **Branded, Biosimilar and Specialised:** To provide specialist support & advice to guide national procurement of branded, biosimilar and specialised medicines.
 - **National Homecare Medicines Committee:** To provide support and input to this committee in order to support the wider homecare market.
 - National Patent Group: To support operational horizon scanning relating to the procurement of new medicines including patent expiry and first-to-market innovative new product pipelines (see MI Function). This information should then be used to support the CMU by informing the contracting process.
- c. Providing specialist medicines assurance advice to support tendering and contracting for all medicines on CMU framework agreements by informing & actively supporting the CMU contracting process.
- d. Supporting commissioners and CMU by responding to local enquiries about all aspects of the management of medicines use and expenditure. The aim is to ensure appropriate transparency and visibility of secondary care contract prices and to support implementation of product switches and changes to facilitate use of "best value" medicines.

The SPS Procurement Function will co-ordinate and contribute to the NHS response to shortages of medicines by working with key stakeholders in line with agreed NHSEI governance structures. This will include working with DHSC and CMU on the management of shortages, supporting trusts with local management, and escalation of new issues as they arise.

The SPS Procurement Function will assist in the management of significant national shortages, through the control of remaining stocks and centrally coordinated allocations.

2. Support to Trust Chief Pharmacists

The SPS Procurement Function will support Trust Chief Pharmacists and their procurement teams to ensure medicines are procured and available for use at the point of need. It will support Trusts with advice and guidance as needed on any aspect of medicines procurement and supply chain operation.





This will be delivered through:

- a. **Leadership**: Providing subject matter expertise in a format which addresses needs, in the delivery of best practice systems and processes for the purchasing, storage, supply and distribution of medicines.
- b. Identification & sharing best practice / standardisation: Assisting and supporting Trusts to obtain best value from the medicines they use, by the provision of data and signposting to best practice, drawing attention to missed opportunities, with particular reference to standardising core procurement functions at a Trust level. This would include the development of template procurement documents (policies, SOPs, guidance).
- c. **Promoting cost-effectiveness:** the provision of regular highlight reports regarding contracting activity, savings opportunities and cost pressures, potential financial implications of terminations and shortages.
- d. Provision of business intelligence and Information: to support trusts in
 - explaining and interpretating procurement strategies and their regional and local impact in order to ensure local implementation of national and regional contracts.
 - Validate, provide and disseminate key intelligence and information about the medicines supply chain.
- Communicating and coordinating local response to national initiatives and communicating and coordinating central responses to local issues.
 - Making recommendations on the implementation and deployment of new and innovative IT solutions to support medicines supply
 - e. **Query answering and escalation:** to ensure that urgent and critical issues are effectively and promptly resolved and/or escalated and addressed at the appropriate level

3. Support to, and liaison with the Pharmaceutical Industry, Consortia, Regional and Local contracting processes

The SPS Procurement Function will, where appropriate to meet identified needs of Trusts within a region:

- a. Work with regional Procurement Hubs to provide subject matter expertise and professional oversight of processes to assist the delivery of frameworks for pharmacy related goods and services which are currently outside of the scope of CMU frameworks.
- b. Facilitate the maintenance of robust and effective networking arrangements between and within with consortia in place for Trust Procurement Leads within regions.
- c. To liaise with commercial suppliers regarding the NHS's requirements for medicines, the introduction of new medicines, packaging and labelling of medicines, pricing and the implementation of procurement contracts.





SPS Quality Assurance (QA) Function

The SPS QA Function will support the continuous quality improvement in the governance arrangements for the safe handling, preparation and purchasing of medicines across the NHS through the provision of advice, best practice guidance and implementation resources. This will be achieved via the following

1. Provision of Advice and Support

The SPS QA function will provide

- a) Specialist QA advice to Trusts which may be ad hoc and on request or in support of specific projects e.g. COVID 19 vaccination and treatment programme
- b) Best practice guidance based on current regulations and professional standards, and in response to Trust requirement
- c) Governance toolkits which include resources to be adapted and implemented locally including:
 - Institutional Readiness Guidance for implementation of new practices
 - Model SOPs
 - Model Worksheets and record forms
 - Model audit checklists
- d) Support to workforce development by
 - Providing instructive and informative subject matter expertise to support training events

The areas of practice in scope for delivery of advice and support include

- Medicines manufacture and preparation under
 - o Section 10
 - o MS Licence
 - Clinical trial regulations

Additional areas of specialist practice include (please note this list is not exhaustive)

- Radiopharmacy
- Clinical Trials
- Advanced Therapy Medicinal Products
- Design and Validation of Clean Room Facilities and Equipment
- Medicines Importation, storage and distribution
- Quality Control
- Stability and shelf life of Medicines
- Medical Gases
- Drug Recalls and defective medicines
- Unlicensed Medicines
- Safe use of injectable medicines in clinical areas

2. System Leadership

The SPS QA Function will aim to effectively influence and shape policy decisions by

- engaging with regional and national groups, bodies and networks
- act as the liaison point between NHS pharmacy teams and regulators

3. Procurement Support





The SPS QA Function will provide support to

- Nationally agreed procurement work and tenders to identify and evaluate quality requirements for purchasing of licensed, unlicensed medicines and aseptic compounding services.
- Direct support to regional and local procurement hub tenders is excluded from the core specification.
 Services can be provided if funded separately and agreed on an individual project basis.

The areas of practice in scope include DHSC, NHSEI, Royal Pharmaceutical Society, British Pharmacopoeia, NHS Specialist Pharmacy Groups and Committees, Medicines and Healthcare Regulatory Agency, General Pharmaceutical Council, Care Quality Commission, regional and local pharmacy networks.

4. Regulatory Inspection: EL Audit

The SPS QA Function will provide

- Regulatory inspection and oversight of unlicensed NHS aseptic and radio pharmacy units i.e. the aseptic preparation of medicines under Section 10 Exemption
- Maintaining and updating the professional standard (Quality Assurance of Aseptic Preparation Services: Standards) for aseptic preparation of medicines in unlicensed aseptic units
- Collating and reporting unlicensed aseptic unit performance metrics from inspections.





SPS Digital Function

The SPS Digital Function will maintain and develop the digital product offer for SPS. It will do this by working both across SPS and with external suppliers (e.g. web developers).

The SPS Digital Function will seek to ensure that, as far as is practical, SPS works consistently to the standards and advice outlined in the NHS Digital Service Manual. For content, the digital team will work across SPS to apply the relevant NHS Digital Advice https://service-manual.nhs.uk/content, and other national and international best practice usability and governance standards.

The SPS Digital Function will:

- 1. Manage a contract with a 3rd party development agency that ensures the continued presence of a modern set of digital tools for SPS. As a minimum these will include:
 - an active website with a rich feature set
 - a campaign email tool
 - business intelligence capabilities
- 2. Work across the SPS functions to produce an annual content roadmap and work programme, to ensure improvement, development, and maintenance of SPS's online content offer. This will outline key themes and offerings, set out activities for improvement of content and enable monitoring of progress.

The roadmap will ensure published content has a defined user need, that work is prioritised within the SPS workplan and that appropriate governance is followed. SPS functions are responsible for ongoing maintenance of content to ensure continuing currency and relevance; they should use business intelligence and support from the digital team to achieve this.

- 3. Work across the SPS functions and with a 3rd party development agency on additional content and feature development. Development areas will include:
 - Medicines Content Tools specific online tools to cover key areas of medicines use for end users.
 - Site and service features that develop the website beyond being solely the home for SPS content and enable users to get more from all SPS has to offer.
 - SPS "where users need us" exploration of users' needs of SPS website content outside of the current online offer, and development of appropriate solutions (e.g. apps and interoperability with other medicines related software).







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