South Central Ambulance Service
NHS Foundation Trust

PURCHASING FOR SAFETY MEDICINES POLICY

South Central Ambulance Service NHS Foundation Trust
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DOCUMENT INFORMATION

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Ratifying committee/group: Medicines Optimisation and Governance Group

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1. Introduction

1.1. The purchase of medicines involves the potential risk for an adverse event, but this risk can and should be minimised.

1.2. The National Patient Safety Agency (now NHS Improvement) recommended that all healthcare organisations implement a “purchasing for safety” policy to promote the procurement of injectable medicines with inherent safety features.

1.3. All NHS pharmacy staff assume a duty of care when supplying a medicine.

1.4. To minimise adverse events, it is essential that possible risks are identified, and assessed, and action taken to minimise the possibility of an adverse incident.

1.5. Part of this process involves ensuring that procurement delivers a medicine of a suitable quality which is well designed for use. Factors include product identification, reconstitution, administration, and disposal.

1.6. It is essential that the procurement process assesses the capabilities of the supply chain to the Trust to ensure that products are genuine, have been correctly stored and are available when required.

1.7. Procurement of medicines is carried out solely by the Pharmacy department.

1.8. All medicines procured for use in the Trust should be licensed wherever possible. Where it is necessary to procure an unlicensed medicine, this should be in line with the Trust Unlicensed Medicine Policy.

1.9. The Trust has a responsibility to ensure that medicines procured by the Trust are suitable for their intended purpose, safe to use and cost effective.

2. Scope

2.1. This policy applies to all staff involved in the administration of medicines, including those that work under a contract for services, and those supplied to do work by a third party, including agency and volunteer staff.

2.2. This policy has been developed as a separate section of CSPP5 Medicines Management Policy, to acknowledge the importance of appropriate procurement of safe medicines.

3. Equality statement

3.1 The Trust is committed to promoting positive measures that eliminate all forms of unlawful or unfair discrimination on the grounds of age, marriage and civil partnership, disability, race, gender, religion/belief, sexual orientation, gender reassignment and pregnancy/maternity or any other basis not justified by law or relevant to the requirements of the post. The Trust will therefore take every possible step to ensure that this procedure is applied fairly to all employees regardless of the afore mentioned protected characteristics, whether full or part time or employed under a permanent or a fixed term contract or any other irrelevant factor.

3.2 By committing to a policy encouraging equality of opportunity and diversity, the Trust values differences between members of the community and within its existing workforce, and actively seeks to benefit from their differing skills, knowledge, and experiences in order to provide an exemplary healthcare service. The Trust is committed to promoting equality and diversity best practice both within the workforce and in any other area where it has influence.

3.3 Where there are barriers to understanding; for example, an employee has difficulty in reading or writing, or where English is not their first language, additional support will be put in place wherever necessary to ensure that the process to be followed is understood and that the employee is not disadvantaged at any stage in the procedure. Further information on the support available can be sought from the HR Department.

4. Aim

4.1. This policy aims to provide guidance for the procurement of medicines and ensure they are risk assessed for their potential to lead to medication errors in use

4.2. The risk assessment forms a critical part of the overall procurement decision making process. It aims to evaluate the medicine, its labelling and packaging to ensure that they are fit for their intended purpose by patients and staff, including prescribing, supplying, preparing, administering, and disposing.

4.3. This policy does not cover the procurement of medical devices.

5. Roles and responsibilities

5.1. Trust Board: Has responsibility and accountability for ensuring the provision of appropriate resources required to implement this policy.

5.2. Head of Pharmacy: designated as having overall responsibility for controlling the procurement and supply of medicines throughout the Trust ensuring that all staff are aware of this policy and that there are mechanisms in place for providing assurance that the policy is followed.

5.3. Lead Pharmacist: 999 services: is responsible for ensuring that all necessary risk assessments have been completed

5.4. Medicines Manager: is responsible for ensuring that the policy is followed when purchasing medicines and that all necessary risk assessments have been completed

5.5. Procurement staff: will work with pharmacy to ensure appropriate governance in terms of sign off on all key tender and contract documents. They are not responsible for the procurement of medicines. All medicines procurement occurs through the pharmacy team

5.6. Medicines Optimisation and Governance Group

5.6.1. Oversee the governance and management of medicines across the Trust
5.6.2. Receive specific issues in relation to the delivery, development and

monitoring of medicines

5.7. Team Leaders:
- 5.7.1. Ensure all staff within their team are aware of, accountable for compliance and adherence with this Policy.
- 5.7.2. Ensure that all staff within their team have read, understood and are accountable for their actions in relation to Trust SOPs
- 5.7.3. Ensure all staff within their team have access to and attend training regarding medicines administration and management.

5.8. All staff: have a duty to follow this policy and report any concerns that may impact on the safety of patients.

6. Definitions

6.1. Licensed medicine: A medicinal product which has been issued with a Marketing Authorisation (previously known as a product licence) by the Medicines and Healthcare Products Regulatory Agency (MHRA).

6.2. Unlicensed medicine: This is a medicinal product which has not been issued with a Marketing Authorisation but is available for clinical use. This product may not been issued with a Marketing Authorisation but is available for clinical use. This product may not be subject to the same stringent controls, quality, and safety assessment as those products with a licence. This category includes imported medicines which may have a licence in another country and specials extemporaneously made and have no licence.

6.3. NHS Commercial Medicines Unit (CMU): The CMU works on behalf of the Department of Health and the NHS to look at the supply and procurement of medicines in hospitals. In particular it works with pharmacists and suppliers to gather and analyse the money spent on medicines.

6.4. Pharmaceutical Quality Assessment (PQA): This assessment is aimed at ensuring the medicine meets the technical specification and is of appropriate quality. The assessment also incorporates medication error potential analysis (MEPA). This element of the assessment process is designed to identify the areas of risk associated with the medicines' labelling and packaging, including user information e.g., Patient Information Leaflets (PIL) and technical data

7. General Principles

7.1. Commercial representatives for medicines must not visit Trust sites unless the relevant manager has given prior agreement. Casual visits are not permitted.

7.2. Introduction of new products are only permitted in accordance with the SCAS Formulary Management Policy

7.3. Medicines must only be procured within agreed valid contracts

7.4. Medicines must only be procured by the Pharmacy team

7.5. Only those medicines approved by the Head of Pharmacy on a Trust approved formulary will be purchased by the Trust.

7.6. Purchased medicines must be ethically sourced and be from a supply source that

can demonstrate regulatory standards throughout their supply chain.

7.7. In all dealings with suppliers and potential suppliers Trust representatives will operate under the highest standards of honesty, integrity, impartiality, and objectivity. Trust representatives should refer to the ABPI Code of Practice and the SCAS Anti-bribery and Fraud Policy FFP2.

7.8. Contracts for medicines must be established in consultation with procurement. Refer to the SCAS Tendering and Quotation Procedure FPP3 for tendering of contracts.

7.9. The Head of Pharmacy must have oversight of new contracts for medicines

7.10. Procurement of medicines must adhere to the Public Contracts Regulations 2015.

7.11. Procurement of medicines must adhere to the Human Medicines Act 2012

7.12. Procurement of medicines must be through a licensed wholesale dealer unless exempted by the Human Medicines Act 2012

7.13. Regional Procurement Specialists can provide advice about potential new suppliers

7.14. The pharmaceutical supplier has the responsibility to ensure that medicines are only supplied on the instruction of an authorised person.

7.15. The process for the ordering of medicines by pharmacy is contained in SOP MED101 and for controlled drugs MEDCD002. Individual SOPs should be developed for the procurement of Investigational Medicinal Products where appropriate.

8. Risk Assessment

8.1. Risk assessment is at the core of any safety policy. The Trust Medicines Risk Assessment Template is in Appendix 1

8.2. A risk assessment should be undertaken by the Lead Pharmacist in consultation with other clinicians who understand the purpose and end use of the product being procured.

8.3. If a medicine is assessed by the Lead Pharmacist as a high risk of causing a patient safety incident, these will be reported to regional QA and procurement specialists, who will use the information as the basis of discussion with the manufacturers about possible changes in presentation

8.4. Risk assessments should consider the following components of safety

8.4.1. Quality of products– is it in accordance with an accepted specification?
8.4.2. Design and use of products - is it “fit for purpose”?
8.4.3. Labelling and packaging of products– have these been assessed by QA and have a low MEPA score?
8.4.4. Source of products and materials
8.4.5. Treatment of product within supply chain

8.4.6. Whether the product is designed as “Ready for Use / Administration”
8.4.7. Product delivery into the Trust
8.4.8. Product storage within the Trust

8.5. Quality of Products
8.5.1. Wherever possible ready-to-use or ready-to administer medicines with a marketing authorization issued by the MHRA are used in preference to an unlicensed product
8.5.2. Exceptions may occur for some products e.g., concentrated products requiring complex calculations and / or manipulations prior to dilution or reconstitution before administration. In these circumstances it may be safer to use an unlicensed but ready to use formulation if one is available from a reputable “specials” manufacturer. Refer to the Unlicensed Medicine Policy

8.6. Labelling and Packaging of Products
8.6.1. The MHRA’s ‘Best practice guidance on labelling and packaging of medicines’ states that ‘The safe use of medicines depends on users reading the labelling and packaging carefully and accurately and being able to assimilate and act on the information presented’.

8.6.2. Common causes of error selection include similar labelling and packaging, lookalike and sound alike brand names.

8.6.3. Despite automation there will always be some manual selection involved in the administration process and therefore pharmacy should take error prevention measures as part of the general risk management process

9. Source of Products

9.1. It is only by using trusted and appropriate sources of supply that the suitability of products purchased can be assured and the possibility of counterfeit or damaged medicines being purchased can be minimized

9.2. Suppliers and wholesalers are required to hold an appropriate license from the MHRA, and this should be checked for authenticity

9.3. Despite automation there will always be some manual selection involved in the administration process and therefore pharmacy should take error prevention measures as part of the general risk management process

9.4. Suppliers and wholesalers are required to hold an appropriate license from the MHRA, and this should be checked for authenticity

9.5. NHS CMU holds a list of inspected suppliers who hold or have successfully held a CMU contract. This database is held on their website. NHS CMU Pharmacy QA and procurement staff inspect potential suppliers. Procurement through the CMU contract is the preferred route of procurement compared to other sources.

9.6. The entire upstream supply chain should be included in these assessment processes as several links may be involved in obtaining the medicine.

9.7. Pharmacy will engage with procurement before selecting or recruiting any third-party suppliers

10. Investigational Medicinal Products

10.1. Investigational Medicinal Products will be procured directly from clinical trial sponsors.

10.2. Clinical trial sponsors must hold the appropriate licenses and adhere to relevant legislation and Good Clinical Practice in the manufacture, importation and distribution of IMPs.

10.3. IMPs will be procured in line with the trial protocol and, where relevant, local Standard Operating Procedures

10.4. The delegation log for a trial is a regulatory document and maintains a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

10.5. Individuals may only receive and distribute an IMP after the authority to do so has been delegated to them, this is recorded on the delegation log and the individual has received appropriate training to do so.

11. NHS Contracts

11.1. All medicines on contract have a product license unless the contract is specifically for unlicensed medicines.

11.2. Pharmacy will engage with procurement before procuring new contracts for medicines.

11.3. Generic medicines that are tendered for NHS contracts are assessed by NHS CMU Pharmacy QA staff according to an assessment tool developed by the National NHS QA Committee and given a PQA score which reflects suitability for use and potential for medication error. (For example, the clarity of the labelling, the suitability for use, the availability of patient information etc.) Branded medicines are not currently assessed unless offered on a generics contract.

11.4. The assessment tool can be obtained from the regional QA pharmacist. The assessments are available on the PharmaQC database.

11.5. Assessed products present a known risk and should be used in preference to those not assessed (and consequently presenting an unknown risk). The Pharmacy team will review risk assessments sent by the supplier before introducing products into the Trust.

11.6. Purchasing “off contract” should only be undertaken with caution and risk assessment. Purchasing “off contract” must only be undertaken under the authorisation of the Head of Pharmacy. The PharmaQC database contains details of assessments and should be used to decide on suitable alternatives to contract lines, should these be unavailable.

12. Delivery and Storage Arrangements

12.1. The Medicines Management Policy and associated Standard Operating Procedures covers the internal supply chain of medicines.

12.2. The Safe and Secure Handling of Medicines Policy covers storage

requirements for medicines within the Trust

13. Medicines Shortages

13.1. There are occasions where there may be medicine shortages; these shortages can be for several reasons such as a merger of pharmaceutical manufacturers, cost of licensing for new generic formulations or lack of raw material

13.2. The Department of Health, CMU or pharmaceutical industry notify Trusts as soon as possible of medicines shortages, together with supporting information in order that any shortages can be managed safely and reduce the risks to patients.

13.3. As a Trust we are not permitted to stockpile medicines as this can destabilize the supply chain.

13.4. Sourcing of alternative brands, similar items or unlicensed alternatives are some of the options available in the event of a shortage. Refer to the Medicines Shortages procedure MED319.

14. Falsified Medicines Directive

14.1. The EU Falsified Medicines Directive (2011/62/EU) (FMD) was adopted in 2011 and introduced new harmonised measures to ensure that medicines in the European Union (EU) are safe and that trade in medicines is properly controlled.

14.2. Following the UK's departure from the EU, the 'safety features' Delegated Regulation (EU) 2016/161 no longer applies in Great Britain (England, Scotland and Wales) but still applies in Northern Ireland.

14.3. FMD ensures the provision of several safety features for almost all prescription-only medicines that aim to prevent falsified medicinal products from entering the pharmaceutical supply chain.

14.4. The safety features are placed on the packaging of the respective medicinal products by the pharmaceutical manufacturer and consist of the following

14.4.1. A unique identifier in the form of a 2D data matrix barcode, allowing the verification of the authenticity and the identification of an individual pack of a medicine

14.4.2. Anti-tampering device (tamper evident features)

14.5. The unique identified comprises:

14.5.1. A product code which allows the identification of at least:

14.5.2. The name of the medicine

14.5.3. The common name

14.5.4. The pharmaceutical form

14.5.5. The strength

14.5.6. The pack size

14.5.7. The pack type

14.5.8. The serial number, which is a numeric or alphanumeric sequence of a maximum of 20 characters randomly generated

14.5.9. A batch number

14.5.10. An expiry date

14.6. The pharmaceutical manufacturer (on behalf of/or the marketing authorization holder) must upload the information from the 2D data matrix barcode into the European data repository after certification and before the product is released for sale or distribution.

14.7. The 2D barcode is then scanned and the anti-tampering device checked at various points in the supply chain to verify that it is an 'authentic' medicine.

14.8. On supply to the patient or upon export or conversion, the unique identifier is 'decommissioned' by scanning the 2D barcode and removing the serial number from the FMD system, thus ensuring that the anti-tampering device is intact when the medicine is dispensed to the patient.

14.9. Medicines with a marketing authorisation valid only in Great Britain (PLGB) do not require a Unique Identifier. However, the MHRA encourages companies to retain the tamper evident device.

14.10. A derogation from the delegated regulation is in effect meaning that the unique identifiers on packs with a marketing authorisation valid in NI, supplied by a manufacturer or wholesaler in the EEA do not require decommissioning when exported to the UK.

14.11. This supports the flow of products through Great Britain to Northern Ireland. Unique identifiers on these packs should be decommissioned in Northern Ireland as required by EU Delegated Regulation 2016/161.

14.12. Therefore, the MHRA and DHNI will also be taking a pragmatic, flexible approach to how we enforce the legal requirements, as long as the normal checks are carried out and there is no reason to think that the medicine is falsified. This position will be kept under review by the MHRA.

14.13. Any electronic scanning solutions implemented in the Trust should have the capability to identify falsified medicines in lien with regulations and guidance at the time of implementation

15. Reporting

15.1. Systems for reporting patient safety incidents in medicines exists both within the Trust and external to it. Internal incidents should be reported in line with the Trust Incident Reporting Policy.

15.2. An explanation of external reporting schemes is given in Appendix 2.

16. Training

16.1. Training will be provided to staff that use the Proactis system

16.2. Staff requiring additional training regarding this policy will be supported by their line manager and the Lead Pharmacist

17. Equality and Diversity

17.1. An initial screen equality and diversity impact assessment has been carried out on this policy and, as per appendix 5, is available on request

18. Monitoring

18.1. The effectiveness of this policy will be monitored through the Medicines Optimisation and Governance Group including incident reports and routine medicines audits.

19. Consultation and Review

19.1. A consultation exercise on the policy will be carried out with the stakeholders every 3 years, or less if there are any relevant changes to legislation or best practice

20. Implementation (including raising awareness)

20.1. The policy will be implemented and communicated to managers and staff within the Trust via the weekly newsletter, Staff Matters. Emails will also be sent to senior managers and area managers asking them to bring the existence of the policy to their staff.

21. Associated documentation

- Adverse Incident Reporting and Investigation Policy v10
- Controlled Drug Policy v6.2
- Medicines Management Policy v8.0
- Patient Group Direction Policy v2.0
- Safe and Secure Handling of Medicines Policy v1.0
- Unlicensed Medicines Policy v1.0
- Formulary and New Medicines Policy v1.0
- SOP MED319 Managing Medicines Shortages

22. Appendix 1: Medicines Risk Assessment

New Medicine Risk Assessment

23. Appendix 2: Reporting Systems

Reporting system	When to use	Examples (not exhaustive)	Report sent to	Contact information
MHRA Counterfeit Case Referral Centre	Suspected counterfeit product		MHRA Counterfeits Case Referral Centre	**Telephone:** 020 3080 6701 (24 hours) Email: counterfeit@mhra.gsi.gov.uk

MHRA Yellow Card Reporting	use the 'side effect' button to report side effects and adverse reactions to medicines, herbal and complementary remedies use the DEFECT button to report issues with product quality	Unexpected adverse drug reactions and side effects. Empty vial or ampoule, errors in labelling	MHRA Yellow Card system	https://yellowcard.mhra.gov.uk/
Minor Defect Reporting Scheme	Minor product defects which are batch specific, with no immediate severe risk to patient safety	Empty blister in strip. Missing batch number or expiry date, syringe filled volumes incorrect	Inform manufacturer. Complete minor defect reporting form and send to regional Quality Assurance service.	Email to pharmacyQAinfo@gstt.nhs.uk
ProMS Potential risk of medicines selection	Incidents where products have been selected or supplied incorrectly, where issues relating to packaging design and presentation are felt to be contributory factors.	Selection of lookalike and sound alike drugs. Manufacturer's packaging has poor differentiation between different products or strengths.	Regional Quality Assurance Service	Email to pharmacyQAinfo@gstt.nhs.uk
Commercial Medicines Unit (CMU)	Issues relating to supply of medications purchased through CMU contracts	Change in manufacturer of product supplied. Financial & contractual issues	Relevant CMU buyer for Trust concerned.	See contact details for individual buyers. http://cmu.dh.gov.uk/

24. Appendix 3: Review Table

24.1. This policy is regularly reviewed and updated with information in line with relevant national guidance and legislation. A full 'Review Table of Contents' is available on request.

25. Appendix 4: Responsibility

25.1. The responsibility for this policy is shared between various Policy Groups, Lead Director/Officers, Working Groups and Committee members.

25.2. A full list of all responsible parties can be made available upon request.

26. Appendix 5: Equality Impact Assessment – Screening

26.1. An initial screening equality impact assessment has been carried out and has identified that the policy does not have an adverse or detrimental impact on any of the proscribed equality groups as the policy is designed to protect all staff who carry out work for or on behalf of the Trust.

26.2. The screening element of the initial 'Equality Impact Assessment' is available on request.

27. Appendix 6: Equality Impact Assessment Form – Section Two – Full assessment

27.1. Due to the outcome of the initial screening equality impact assessment, it has not been necessary to carry out a full equality impact assessment.

28. Appendix 7: Ratification

Policy Title: Purchasing for Safety Policy

Author's Name and Job Title: Victoria Bray, Consultant Pharmacist

Review Deadline: 26/05/22

Consultation From – To (dates): 21/09/2022 – 12/10/2022

Comments Received? (Y/N): Y

All Comments Incorporated? (Y/N): Y

If No, please list comments not included along with reasons:

Equality Impact Assessment completed (date): 07.07.22
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Name of Accountable Group: Medicines Optimisation and Governance Group

Date of Submission for Ratification: 26/05/22

Template Policy Used (Y/N): Y

All Sections Completed (Y/N): Y

Monitoring Section Completed (Y/N): Y

Date of Ratification: 13/10/2022

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Date Next Review Due: 20/03/2024

Signature of Accountable Group Chair (or Deputy):

Name of Accountable Group Chair (or Deputy): Louise Maunick