University Hospitals of Leicester NHS
NHS Trust

Pharmacy Purchasing for Safety Policy

(For licensed and unlicensed medicines)

Approved By:	CSI Quality and Safety Board
Date of Original Approval:	**June 2017**
Trust Reference:	**C30/2017**
Version:	V2
Supersedes:	V1
Trust Lead:	Elizabeth McKechnie, Medication Safety Pharmacist
Board Director Lead:	Dr Andrew Furlong, Medical Director
Date of Latest Approval	September 2023
Next Review Date:	**September 2026**

CONTENTS

Review

2019 :

- 4.3 Change in titles of staff responsible for policy
- Supporting references and monitoring table updated
- Updated appendix 1

KEY WORDS

Purchasing, medicines, safety, unlicensed medicines, procurement, drugs

1 INTRODUCTION

1.1 This document sets out the Policy of the Pharmacy Department within University Hospitals of Leicester (UHL) NHS Trust for the safe purchase of medicines

1.2 The use of all medicines carries the risk of a patient safety incident (such as inappropriate reconstitution or administration) as well as the more usually considered adverse events such as side effects. These risks can and should be minimised.

1.3 To enable this it is essential that all risks are identified and assessed and action taken to minimise the possibility of a patient safety incident.

1.4 Part of this process is to ensure that the procurement of medicines provides so far as is possible medicines which are of suitable quality, and are safe in use i.e. prescribing, dispensing, preparation, administration and disposal.

1.5 Moreover it is essential that the procurement process assesses the capabilities of the upstream supply chain to ensure products are genuine, stored correctly and available when required.

1.6 Risk assessment is at the core of any safety policy. A risk assessment should be undertaken by staff with a full understanding of the purpose and end use of the product being procured.

1.7 Risks should be identified and minimised, reporting systems should be available and acted upon, and if normal sources are not available (e.g. in a shortage situation) then alternatives need to be assessed in the light of the increased risk they may present to patients. Please refer to Pharmacy SOP 503 Process for Handling Drug Shortages available on INsite.

1.8 If a product is assessed locally as a high risk of causing a patient safety incident this should be reported to regional quality assurance, (QA) and procurement specialists. These products can then form the basis of discussion with the manufacturers about possible changes in presentation.

2 POLICY SCOPE

2.1 The policy applies to all pharmacy staff involved in purchasing or assessing the use of medicines.

2.2 This policy covers the procurement of licensed and unlicensed medicines and any medical devices which are purchased via the Pharmacy Purchasing Office for UHL Pharmacy & TrustMed Pharmacy.

3 DEFINITIONS

3.1 Licensed Medicine

A medicinal product which has been issued with a Marketing Authorisation (formerly known as a Product License) by the Medicines and Healthcare Products Regulatory Agency (MHRA).

3.2 NHS Commercial Medicines Unit (CMU)

The CMU sits within the Specialised Commissioning Directorate of NHS England and works on behalf of 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 secondary care medicines.

3.3 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 a PQA score. 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.

3.4 Unlicensed Medicine

A medicinal product which has not been given a Marketing Authorisation but is available for clinical use, and which may not be subject to the same stringent controls, quality and safety assessments as those products with a licence.

4 ROLES AND RESPONSIBILITIES

4.1 The executive lead responsible for this policy is the **Medical Director**

4.2 **The Chief Pharmacist** is designated as having overall responsibility for controlling the procurement and supply of medicines throughout the Trust ensuring that

a) all relevant staff are aware of this policy

b) there are mechanisms in place for providing assurance that the policy is followed.

4.3 The **Deputy Chief Pharmacist Medicines Optimisation** and the **Principal Pharmacy Technician Business Services** are responsible for ensuring that the policy is followed when purchasing medicines and that all necessary risk assessments have been completed.

4.4 **Clinical Management Group (CMG) lead pharmacists** and other **advanced specialist pharmacists** working with Medicines Information staff will support the safe introduction of a new medicine within their CMG.

4.5 **Pharmacy staff**

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

5 POLICY IMPLEMENTATION AND ASSOCIATED DOCUMENTS

5.1 Components of safety

Risk assessments should take account of the following factors

- Quality of Products
- Design and Use of Products (e.g. ready-to-use and ready-to-administer products)
- Labelling and Packaging of Products
- Source of Products and Materials
- Treatment of Product within Supply Chain
- Product delivery into the pharmacy
- Product storage within the hospital
- Product distribution.

5.2 Licensing

a) The default position should always be that a ready-to-use or ready-to-administer medicine with a product licence (or a devices licence) issued by the MHRA should be used in preference to an unlicensed product

b) Exceptions may occur for some high risk products, for example licensed 'concentrate' products requiring complex calculations or manipulations prior to dilution or reconstitution in clinical areas before they can be administered to patients may not be safer in use than unlicensed ready-to-use or ready-to-administer formulations of the same medicine.

c) If an unlicensed formulation has to be used then it should be procured under a bespoke procedure for unlicensed medicines that takes into account the increased risks with

these types of products and that responsibility for their use lies with the Trust (see Unlicensed Medicines Policy B29/2004)

5.3 Products on NHS contracts

a) All medicines on contract have a product licence and all medical devices on contract are CE marked, unless the contract is specifically for unlicensed medicines. Generic medicines that are tendered for NHS contracts are assessed by NHS 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.

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

c) Assessed products present a known risk and should be used in preference to those not assessed (and consequently presenting an unknown risk).

d) Purchasing “off contract” should only be undertaken with caution and risk assessment. The PharmaQC database contains details of assessments and should be used to decide on suitable alternatives to contract lines, should these be unavailable.

5.4 Reporting Systems

a) Systems for reporting patient safety incidents and defects in medicine and medical devices exist both within the trust and external to it.

b) Internal incidents must be reported using the Trust Incident reporting systems, Datix web.

c) See appendix 1 for external reporting schemes.

5.5 Source of Products

a) Trusted and appropriate sources of supply should be used by procurement to ensure the suitability of products purchased can be assured and the possibility of counterfeit or damaged medicines being purchased minimised

b) Suppliers and wholesalers are required to hold an appropriate licence from the MHRA and this should be checked for authenticity. NHS CMU holds a list of suppliers who hold or have successfully held a CMU contract.

c) The database (NHS SID) is held on the CMU website. Pharmacy QA and procurement staff are able to inspect potential pharmaceutical suppliers and these reports can be used to assess new suppliers.

d) Pharmacy procurement specialists can give advice about potential new suppliers. The entire upstream supply chain should be included in these assessment processes as several links may be involved in obtaining the medicine.

5.6 “Ready-to-Use”/ “Ready to Administer”

a) Although many medicines are licensed and come from a suitable supplier there may be differences in the presentation.

b) Risk assessment should involve the complete use of the medicine. That is the identification, reconstitution, administration and disposal in the clinical settings in which it is used. This is important for all medicines but particularly those that have been identified as representing a high risk under the NPSA (National Patient Safety Agency now part of NHS Improvement) assessment guidance.

c) Medicines which represent the minimum risk throughout the whole of this process should be preferred.

d) Where possible higher risk products should be prepared (e.g. reconstituted) either in house by the Pharmacy Manufacturing Unit or by commissioning a (licensed and suitable) manufacturer to prepare the medicine in a suitable format to minimise the risk.

e) If gaps in this risk process are identified the products involved should be reported to the regional procurement specialist who can compile lists of these products and engage industrial solutions where possible.

5.7 Delivery and Storage Arrangements

a) All the above points concentrate on the "external" supply chain. That is the part of the supply chain outside the Trust.

b) It is equally important though to ensure that the "internal" supply chain is robust and fit for purpose; that is the arrangements ensure products are available, fit for purpose when they are required for patients.

c) The Safe and Secure Handling of Medicines (revised Duthie report, published by the Royal Pharmaceutical Society of Great Britain and available on their website at www.rpharms.com) covers the requirements of the internal supply chain and storage and distribution arrangements should comply with this document.

5.8 Procedure

a) All new medicines to the Trust must go through the process of a risk assessment alongside the submission to the Therapeutic Advisory Service (TAS) and at the time of completion of the New Product Request Form. The risk assessment form to be used is included as Appendix 2.

Additional risk assessments are required as follows:

- All new unlicensed preparations must be assessed following the Policy for Unlicensed Medicines (Trust ref B29/2004). Refer to the Chief Pharmacy Technician for Unlicensed Medicines and Senior Pharmacy Technician for Unlicensed Medicines.
- All new injectable products must have a NPSA risk assessment carried out by the CMG lead pharmacist from the main directorate requesting the product. (Appendix 3)

b) The results of all risk assessments to be recorded on a central database (register) held by the Pharmacy Department. Products assessed as High Risk to be referred to the monthly Pharmacy Quality & Safety Board for approval of mitigating actions.

c) Alternative products/ presentations must be sourced, if available, for high risk products or risk reduction management strategies identified and ready for implementation prior to procurement and approval from Therapeutic Advisory Service (TAS).

d) Decisions made by the Pharmacy Quality & Safety Board about purchasing and risk reduction strategies must be documented on the risk assessment documented and filed in the central database (see 5.8b)

5.9. Suggested Actions for High Risk Rated Products

- Purchase a safer alternative where possible.
- Identify any risk reduction measures e.g. issue "caution in use".
- Advise end users to perform a local risk assessment on the product.
- Change local practice if necessary (e.g. storage in different locations, ward briefings etc)

- Monitor effectiveness of risk management measures using local error reporting mechanisms.

6 EDUCATION AND TRAINING REQUIREMENTS

6.1 All relevant staff must have read and understood this policy and the procedures therein.

7 PROCESS FOR MONITORING COMPLIANCE

The following table lists the monitoring arrangements for this policy:

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements
Datix Incidents relating to medication errors due to procurement	Chief Pharmacy Technician Quality & Safety	Datix	Monthly	Pharmacy Quality & Safety Board & Medicines Optimisation Committee

8 EQUALITY IMPACT ASSESSMENT

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

- Unlicensed Medicines Policy B29/2004
- Leicestershire Medicines Code
- Pharmacy SOP 501 Procedure for Requesting Any New Product (Licensed & Unlicensed) to be Set Up on All Pharmacy Electronic Computer Systems
- Pharmacy SOP 503 Process for Handling Drug Shortages
- The Royal Pharmaceutical Society's Professional Guidance on the Safe & Secure Handling of Medicines

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

10.1 The updated version of the Policy will be uploaded and available through INsite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trusts PAGL system

10.2 This Policy will be reviewed every three years or sooner in response to clinical or risk issues.

Error reporting systems available and when to use them:

REPORTING SYSTEM	When to Use	Examples (not exhaustive list)	Report Sent To	Contact Information
MHRA Defective Medicines Reporting Centre	Suspected or actual product defect where patient safety clearly at risk	Serious unexpected reaction. Severe, visible microbial or particulate contamination. Suspected counterfeit product.	MHRA Defective Medicines Reporting Centre	Office Hours 020 7084 2574 020 7084 2676 (Fax) Weekends, Public Holidays, Night 020 7210 5371 (to contact duty officer)
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.	Inform manufacturer. Complete minor defect reporting form and send to regional Quality Assurance service.	London, Eastern & South East, Specialist Pharmacy Services, Quality Assurance, Guys Hospital, SE1 9RT, Fax: 0207 1885 041 OR Rob Lowe, QA Specialist Pharmacist, University of East Anglia, Robert.lowe@uea.ac.uk
CMU	Issues relating to supply of medications purchased through CMU contracts.	Change in manufacturer of product supplied. Financial and contractual issues. Product acceptability issues.	Relevant CMU buyer for Trust concerned.	pharmacyqueries@dh.gsi.gov.uk See contact details for individual buyers.
Datix Incident Report	All adverse patient incidents and near misses involving medicines	Administration error, dispensing error, reconstitution error. Wrong drug, wrong dose, wrong route.	NRLS	

Appendix 2 – Risk assessment tool

Tool for assessing the in-use patient safety characteristics of medicines and medicinal products

Product	Assessment completed by	Date

No	Themes	Assessment	Details/ notes
A	**Licensing status**		
A1	Does the product have a UK marketing authorisation?	Yes ☐→A2 No ☐→A3	
A2	Is it only going to be used within that marketing authorisation?	Yes ☐→B No ☐→A3	
A3	Is there a suitable product available with a marketing authorisation for the intended use?	Yes ☐ No ☐	
A4	Is the anticipated use supported by a reasonable evidence base?	Yes ☐ No ☐	
A5	Is technical and patient information available in English to support the anticipated use?	Yes ☐ No ☐	
A6	Do you have assurance of pharmaceutical quality? For example, • If the medicine is unlicensed, is the supplier of the medicine suitably licensed? • What type of assurance process does the manufacturer have in place?	Yes ☐ No ☐	
B	**Name, packaging and labelling, and other pharmaceutical issues**		
B1	Could the medicine's names be confused with those currently in existence? *[Is there risk of sound alike/look-alike errors?]*	Yes ☐ No ☐	
B2	Is the medicine's generic name clearly identifiable in English on the packaging?	Yes ☐ No ☐	
B3	Is other critical information also clearly identifiable in English on the packaging? (e.g. strength, form, any product specific warnings)	Yes ☐ No ☐	
B4	Is the critical information above clear on all sides of the packaging as well as on the primary (e.g. ampoule) and secondary (e.g. carton) packaging	Yes ☐ No ☐	
B4	For branded medicines, is the generic name also suitably prominent?	Yes ☐ No ☐	
B5	Is pharmaceutical information such as the batch number, expiry date, and storage conditions clear and unambiguous on the packaging?	Yes ☐ No ☐	
B6	Where medicines contain more than one active ingredient, are all generic constituents clearly stated on the packaging?	Yes ☐ No ☐	
B7	Is the expression of strength on the packaging consistent with prescribing practice?	Yes ☐ No ☐	
B8	Does the packaging encourage (or at the least not hinder) differentiation between a range of products from a single supplier, or between different products from different suppliers? *[Is there risk of selection errors?]*	Yes ☐ No ☐	
C	**Information provided with the product**		
C1	Is an English language patient information leaflet available with the product?	Yes ☐ No ☐	
C2	Is English language prescribing information available for the product?	Yes ☐ No ☐	
C3	Is appropriate technical information available in English at the point of care to guide calculations, preparation, and administration?	Yes ☐ No ☐	
C4	Does the product information only contain positive statements about use? For example "for intravenous use only" as opposed to "not for intrathecal use"	Yes ☐ No ☐	
D	**Prescribing risks**		
D1	Is the product an additional treatment option, or is it replacing another product or drug?		
D2	Are there issues associated with non-familiarity or confusion with existing treatments?	Yes ☐ No ☐	
D3	Is the dosing and prescribing complex?	Yes ☐ No ☐	
D4	Who will prescribe the item? *[consider prescriber's scope of practice and processes involved]*		
D5	Is the prescribed dose consistent with the way the strength, form, and (where applicable) base salt are presented?	Yes ☐ No ☐	
E	**Known risks and management**		
E1	Has the item (or any similar product) been the subject of any medicines safety alerts? *[e.g. NPSA report, description as a never event, or inclusion in a MHRA drug safety bulletin]*	Yes ☐ No ☐	
E2	Is the medicine under intensive regulatory surveillance?	Yes ☐ No ☐	
E3	Are new or amended clinical or laboratory monitoring requirements associated with the introduction of the medicinal product?	Yes ☐ No ☐	
E4	Is there potential for significant harm in deliberate or inadvertent overdose? If yes, • Are suitable reversibility and antidote strategies available? • Are clinical management strategies in such circumstances defined?	Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐	
E5	Where necessary, is additional patient information available to support safe use of the medicine? For example, are steroid or lithium cards present if necessary?	Yes ☐ No ☐ NA ☐	

F	**Preparation, Calculation, Labelling & Information**		
F1	Are there current known operator safety issues with the drug? • Is the medicine of a class where operator safety issues might be a concern? • Is the medicine subject to COSHH regulations, for example?	Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐	
F2	Is the medicine supplied to the end user in a presentation that is • ready-to-use (i.e. correct volume and correct strength and is ready to draw up) or • ready-to-administer (i.e. in a final container ready for administration to the patient)?	 Yes ☐ No ☐ Yes ☐ No ☐	
F3	In the form presented, are commonly used doses easy to measure?	Yes ☐ No ☐	
F4	If manipulation is required prior to administration, • is it complex (i.e. does it have 5 or more defined steps)? • does it involve any special or unusual complexities (using the contents of part ampoules or vials, complex dilution or mixing with other drugs, or need to crush preparations or make other extemporaneous products prior to administration)?	 Yes ☐ No ☐ Yes ☐ No ☐	
F5	Is a complex calculation (i.e. has more than one step) necessary prior to preparation and/or administration?	Yes ☐ No ☐	
F6	Does the product easily enable essential labelling to be in place at point of administration?	Yes ☐ No ☐	
G	**Administration**		
G1	Is administration of the product in any way complex?	Yes ☐ No ☐	
G2	Is the route of administration of the product intrinsically high risk (such as intrathecal)?	Yes ☐ No ☐	
G3	Does administration require the use of a device and/or disposables? If yes, are there any issues related to their use?	Yes ☐ No ☐ Yes ☐ No ☐	
G4	For injectable medicines, • is the rate of administration safety critical? If yes, what mechanisms are in place to ensure the rate is correct? • is any specific monitoring required during administration? If yes, is it practical & achievable?	 Yes ☐ No ☐ Yes ☐ No ☐	
H	**Supply chain issues**		
H1	Is the product readily and reliably available from a recognised supplier?	Yes ☐ No ☐	
H2	Are expiry dates (both for the product in its original form, and in-use as necessary) available and clear?	Yes ☐ No ☐	
H3	Are there any specific storage requirements? e.g. refrigeration, space (if bulky)	Yes ☐ No ☐	
H4	Are there any issues relating to secure storage? e.g. is there likelihood of misappropriation?	Yes ☐ No ☐	
H5	Overall, consider whether the storage requirements can likely be met?	Yes ☐ No ☐	
I	**Disposal**		
I1	Does the product pose any special risks during disposal to either the user or staff?	Yes ☐ No ☐	
I2	Are there any specific disposal requirements for the product?	Yes ☐ No ☐	
J	**Impact of setting**		
J1	Is the product for use in a highly specialist environment? For example in neonates, fluid restricted patients, or those in critical care scenarios. If yes, is there the potential that it will be used outside such an environment? Have issues associated with such use been identified and addressed?	Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐	
J2	Is the medicine one which is likely to be used across other boundaries of care? If yes, have issues associated with such use been identified and addressed?	Yes ☐ No ☐ Yes ☐ No ☐	
J3	Is the medicine one for which self-administration by patients is a possibility? Have any issues associated with such use been identified and addressed?	Yes ☐ No ☐ Yes ☐ No ☐	
J4	Where the manipulation of the product is complex, is the environment in which it is to be prepared conducive to its safe use? That is, will it be as free as possible from distractions and is it an otherwise suitable environment for complex manipulation?	Yes ☐ No ☐	
K	**Summary & Outcome** (Committees involved; whether or not approved for use in the organisation etc)		
K1	As a consequence of the product's introduction, will any changes to practice occur? If yes, are those changes likely to introduce new risks? Or do they have the potential to address patient safety risks known to be present currently?	Yes ☐ No ☐	
K2	Overall, when considered against the status quo, are the risks identified in relation to the product's introduction reasonable?	Yes ☐ No ☐	
K3	Where it is possible to assess, are any patient safety risks outweighed by the potential clinical benefits the product offers against available alternatives?	Yes ☐ No ☐	
K4	Other comments and actions		

Appendix 3

SUGGESTED RISK REDUCTION METHODS THAT CAN BE USED TO MINIMISE RISKS WITH INJECTABLE MEDICINES

1. Simplify and rationalise the range of products and presentations of injectable medicines. Where possible, reduce the range of strengths of high-risk products and provide the most appropriate vial/ampoule sizes

2. Provide ready-to-administer or ready-to-use injectable products – this will minimise preparation risks and simplify administration

3. Provide dose calculating tools – for example, dosage charts for a range of body weights that eliminate the need for dose calculations

4. Provide additional guidance on how to prescribe, prepare and administer high-risk injectable medicines

5. Consider the provision of pre-printed prescriptions or stickers – this will help to ensure that information on the prescription about preparation and administration of high-risk products is clearer

6. Provide locally approved protocols that clarify approved unlicensed and 'off-label' use of injectable medicines

7. Use double-checking systems – an independent second check from another practitioner and/or the use of dose-checking software in 'Smart' infusion pumps and syringe drivers

8. Use an infusion monitoring form or checklist – this will help to ensure that infusions are monitored throughout administration

Proforma : Risk assessment summary for high and moderate-risk injectable medicines products

Name of clinical area	Directorate:	Date:

Risk factors															
Prepared injectable medicine	**Strength**	**Diluent**	**Final volume**	**Bag/syringe**	Therapeutic risk	Use of concentrate	Complex calculation	Complex preparation	Reconstitute vial	Part/multiple container	Infusions pump or driver	Non-standard infusion set	**Risk assessment score**	**Risk reduction method(s)**	**Revised score**
					✓	✓	✓	✓	✓	✓	✓	✓			

Risk assessment undertaken by:	Name of pharmacist:	Name of clinical practitioner:

	Risk factors	Description	✓
1	**Therapeutic risk**	Where there is a significant risk of patient harm if the injectable medicine is not used as intended.	
2	**Use of a concentrate**	Where further dilution (after reconstitution) is required before use, i.e. slow iv bolus not appropriate.	
3	**Complex calculation**	Any calculation with more than one step required for preparation and/or administration, e.g. microgram/kg/hour, dose unit conversion such as mg to mmol or % to mg.	
4	**Complex method**	More than five non-touch manipulations involved or others including syringe-to-syringe transfer, preparation of a burette, use of a filter.	
5	**Reconstitution of powder in a vial**	Where a dry powder has to be reconstituted with a liquid.	
6	**Use of a part vial or ampoule, or use of more than one vial or ampoule**	Examples: 5ml required from a 10ml vial or four x 5ml ampoules required for a single dose.	
7	**Use of a pump or syringe driver**	All pumps and syringe drivers require some element of calculation and therefore have potential for error and should be included in the risk factors. However it is important to note that this potential risk is considered less significant than the risks associated with not using a pump when indicated.	
8	**Use of non-standard giving set/device required**	Examples: light protected, low adsorption, in-line filter or air inlet.	
	Total number of product risk factors	Six or more risk factors = high-risk product (Red). Risk reduction strategies are required to minimise these risks. Three to five risk factors = moderate-risk product (Amber). Risk reduction strategies are recommended. One or two risk factors = lower-risk product (Green). Risk reduction strategies should be considered.	

Appendix 4

RISK ASSESSMENT PROCESS FOR NEW MEDICINAL PRODUCTS TO UHL