East Lancashire Hospitals NHS
NHS Trust

Pharmacy Services

ELHT Pharmacy Purchasing for Safety Policy and Procedure

Policy

The purpose of this purchasing for safety policy is to provide guidance for the purchase and supply of unlicensed medicines and to ensure they are risk assessed for their potential to lead to medication errors in use.
This 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 use by patients and by those handling the product (including prescribing, dispensing, preparing, administering, and disposing).

All unlicensed medicinal products procured via the East of Midlands and Northwest framework agreement for the supply of imported medicines (not licensed in the UK) have been risk assessed according to the NHS medicines procurement QA policy and procedures. If required, data on individual product assessments may be obtained from Quality Assurance North West.

Wherever possible only the following products will be procured for use within the Trust:-

- Injectable medicines that include technical information on how they should be prepared and administered.
- Medicines which are designed in such a way as to promote safer practice
- Ready-to-administer or ready to use medicines
- Unlicensed medicines where no suitable licensed alternative is available which have been risk assessed and approved for use by a pharmacist according to the Trust unlicensed medicines policy

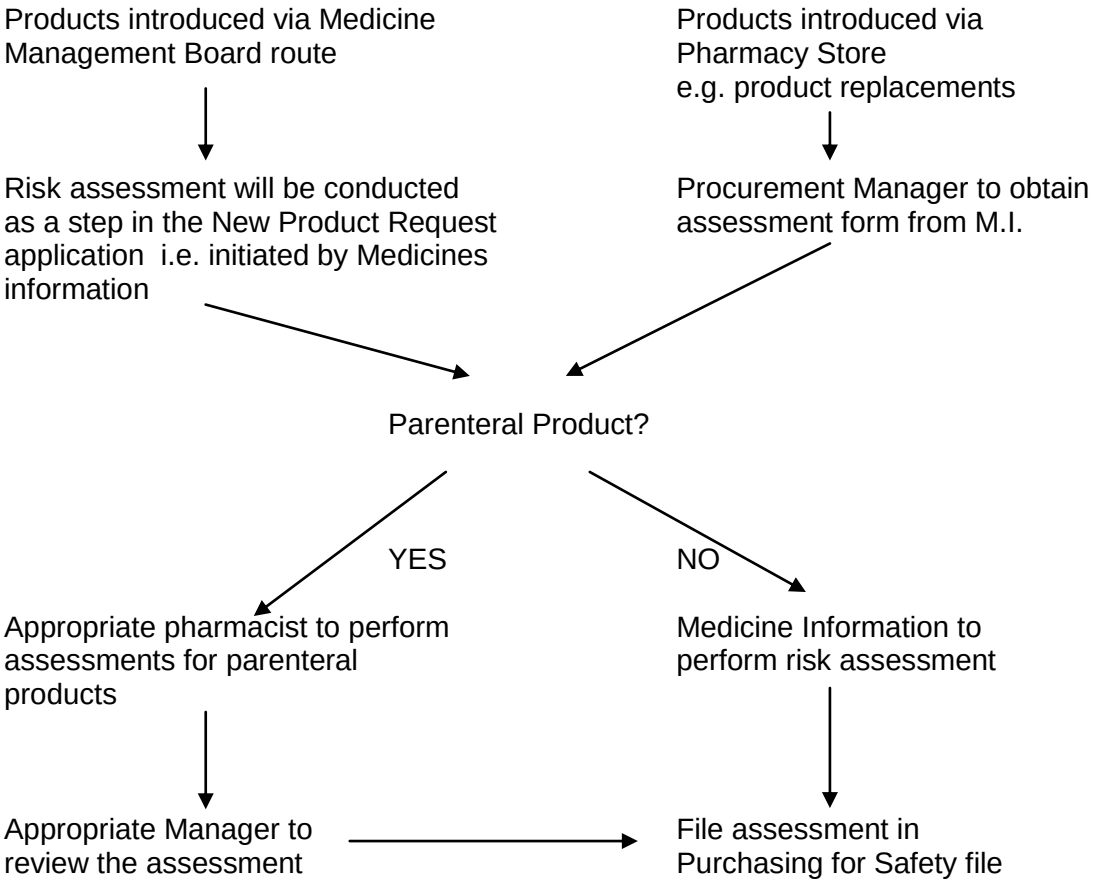
Roles and Responsibilities

Medicines Information (MI) Manager is responsible for management of documentation and initiating risk assessment of new products entering via the Medicines Management Board (MMB) route if appropriate.
Pharmacy procurement team will inform the Assistant Director of Pharmacy/Medicines Information Manager if non MMB approved products require risk assessment.

Assessment Pathway

This policy applies to unlicensed medicinal products not procured on the framework agreements.

Prior to taking a new product into use within the Trust, a risk assessment for the medication error potential with that product will be undertaken according to the following pathway (see next page)



Risk Assessment

The assessment is aimed at evaluating the medicine and packaging to ensure that they are fit for their intended use by the end users and for their potential to lead to medication errors in use. The assessment encompasses the quality of the medicine, user information, and indications. It is designed to identify the areas of risk associated with the medicines' labelling and packaging, including the PIL and administration details.

The risk assessment is designed to evaluate individual medicines, corporate livery issues (e.g. drug, form and strength differentiation) and livery differentiation issues between different suppliers/manufacturers.

The risk assessment is performed only by authorised personnel who have a full understanding of the purpose and use of the product and access to medication incident reporting intelligence within the Trust.

The Assessment Process
The risk assessment is split into nine sections:

- Critical information
- User information
- Pack design
- Corporate livery
- Dose administration
- Technical data
- Product quality
- Licensing
- Robot compatibility

A risk assessment for each section must be carried out and the results entered into the summary spreadsheet (appendix 2). A checklist must be used for this process (appendix 1).

For each section, the risk should be categorised as Critical (C), Major (M), Minor (0) or satisfactory (S). If no risk assessment is carried out in for a particular section, a 'not assessed' (N/A) entry should be made.

Each section in the checklist is split into two criteria; essential and desirable. Any deficiencies in the essential criteria will lead to a critical or major risk rating for that section. Deficiencies in the desirable criteria will lead to a minor rating. Multiple failings in the desirable criteria may lead to a major rating.

Any point of concern should be documented in the comments section of the risk assessment summary spreadsheet to allow other assessors to review the issue.

NB Every risk component will not necessarily be relevant to the medicine under assessment.

The assessor should then review the overall risk to the patient, based on the cumulative risk issues from each section. Overall risk should be categorised as High (H), medium (M) or Low (L).

High Risk - There is a significant error potential and risk to patient safety. *The product should not be ordered unless there is no alternative and effective risk reduction measures are implemented.*
If any single risk category is deemed to be a critical risk, the product is automatically assigned a high overall risk rating.

Medium Risk - There is a low/medium risk to patient safety, but there are medium/major risk issues that need to be addressed by the company. (If there is an equivalent product with a low risk from another manufacturer, then that product should be ordered).

Low Risk - No major risks identified. Safe to be ordered without any corrective course of action.

Reporting of Results
The overall risk assessment for each product is entered into the spreadsheet. The spreadsheet will be reviewed periodically by the Pharmacy Governance Group.

Medium/High Risk Rated Products
Where it is considered necessary to purchase a medicine having a medium or high medication error potential, the following action should be taken:

- Purchase a safer alternative where possible.
- Add to the Pharmacy Risk Register and perform an ELHT risk assessment

To include- Identify any risk reduction measures
Where appropriate advice 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.
- Inform Quality Assurance North West so that action can be taken to notify the regulatory body, Patient Safety Agency (PSA), suppliers, and other Trusts as appropriate.

ELHT Pharmacy Purchasing for Safety Procedure **Appendix 1**

Risk Assessment checklist **Completed by:** **Date:**

Product Description	
Manufacturer/Source	

1. **Critical information:** Critical information is defined as-
   - The name of the medicine
   - The strength of the medicine
   - The form of the medicine
   - The route of administration
   - Posology
   - Warnings

Essential

	✓ or X or N/A
• All critical information must be present (this includes small containers such as ampoules and vials).	
• The name of the medicine expressed on the packaging should be the same as registered in the summary of product characteristics (SPC). No Abbreviations.	
• If the medicine contains more than one active ingredient, all generic names should be clearly stated on the pack.	
• Strengths should be clearly expressed and unambiguous. For injections, the strength should be expressed as total quantity per total volume. Trailing zeros should not be used. Microgram doses should be spelt out rather than abbreviated. (NB pay special attention to different strengths/concentrations across injection product ranges).	
• Base and salt strengths should be clearly defined where appropriate.	

Desirable

	✓ or X or N/A
• The brand name should not be similar to another generic or brand name in either appearance or sound.	

Risk categorisation

Critical (C), Major (M), Minor (0) or satisfactory (S)	

Any deficiencies in the essential criteria will lead to a critical or major risk rating for that section. Deficiencies in the desirable criteria will lead to a minor rating. Multiple failings in the desirable criteria may lead to a major rating.

2. User Information

Essential

	✓ or X or N/A
• Only positive statements should be used on labels e.g. 'For intravenous use only'. Negative statements such as 'not for intrathecal use' should not be used.	
• All patient packs should include a patient information leaflet (PIL).	

Desirable

	✓ or X or N/A
• The design and layout of the PIL should allow the patient to easily find and understand the important messages within the leaflet.	

Risk categorisation

Critical (C), Major (M), Minor (0) or satisfactory (S)	

Any deficiencies in the essential criteria will lead to a critical or major risk rating for that section. Deficiencies in the desirable criteria will lead to a minor rating. Multiple failings in the desirable criteria may lead to a major rating.

3. Pack Design

Essential

	✓ or X or N/A
• The critical information should be given due prominence and located together in the same field of view where practicable (i.e. these items should not be broken up by additional information, logos, background texts or graphics).	
• When the name of the medicine is a Brand name, the generic name of the active ingredient should be given due prominence and should immediately follow the brand name on the pack. There should be no intervening text.	
• The generic name and strength should appear on at least three non-opposing sides of pack (including "shelf" end).	
• The marketing authorisation and name and address of the licence holder should be present on the pack.	
• The batch number and expiry date should be present and legible.	

Desirable

	✓ or X or N/A
• When relevant, colour should only be used judiciously to aid identification (consider innovative designs). • For blister/strip packs, the name & strength of the medicine should be printed legibly over each blister or oriented repeatedly across strip.	
• Ampoules should be labelled longitudinally.	
• Patient packs should have a space for placement of the dispensing label. This should be a blank white space in which there is no text, to aid legibility of the dispensing label. Where it is not possible to employ a blank space, the pack should be of a colour that will not interfere with the readability of the dispensing label.	

Risk categorisation

Critical (C), Major (M), Minor (0) or satisfactory (S)	

Any deficiencies in the essential criteria will lead to a critical or major risk rating for that section. Deficiencies in the desirable criteria will lead to a minor rating. Multiple failings in the desirable criteria may lead to a major rating.

4. Corporate Livery

Essential

	✓ or X or N/A
• There should be good visual differentiation between different medicines within the corporate livery of the company. Consideration should be given to similar or look-alike names (INN and Brand) and potential problems associated with storage due to alphabetical location.	
• There should be good visual differentiation between strengths within the product range.	
• There should be good visual differentiation between different formulations of the same product intended for different parenteral routes (e.g. intravenous and intrathecal).	

Desirable

	✓ or X or N/A
• There should be good differentiation between dosage forms within product range.	

Risk categorisation

Critical (C), Major (M), Minor (0) or satisfactory (S)	

Any deficiencies in the essential criteria will lead to a critical or major risk rating for that section. Deficiencies in the desirable criteria will lead to a minor rating. Multiple failings in the desirable criteria may lead to a major rating.

5. Dose Administration

Essential

	✓ or X or N/A
• Instructions for dosage manipulation should be clear and unambiguous (consideration should be given as to who will be administrating the medicine).	
• If complicated calculations are required to calculate the dose (e.g. dilutions, conversions from milligrams to millimols, mg/kg dosing in children etc.), unambiguous instructions, conversion tables and/or labelling should be provided.	
• If specific end user counselling is required, clear patient instructions should be provided to aid this process (e.g. inhalation devices used in asthma treatment).	
• If additional devices are required to administer a dose, they should be supplied with the medicine along with clear instructions for their use.	

Desirable

	✓ or X or N/A
• Medicines should be in a ready to administer dosage form whenever possible. If reconstitution or serial dilution is required, instructions must be prominent, clear and unambiguous.	
• The Summary of Product Characteristics or specific user guidance should be included in the packaging for medicines requiring further manipulation by health professionals (e.g. fluid compatibility and infusion rates for injections).	

Risk categorisation

Critical (C), Major (M), Minor (0) or satisfactory (S)	

Any deficiencies in the essential criteria will lead to a critical or major risk rating for that section. Deficiencies in the desirable criteria will lead to a minor rating. Multiple failings in the desirable criteria may lead to a major rating.

6. Technical Data

Essential

	✓ or X or N/A
• Displacement values should be provided for any injection requiring reconstitution.	
• Diluent compatibility data should be provided for any injectable dosage form that requires dilution or reconstitution prior to infusion.	
• The recommended diluent should be clearly stated in the SPC and/or packaging.	
• The shelf life and specified storage conditions following opening or reconstitution should be clearly stated in the SPC and on the packaging.	
• The product should be latex-free. If latex is present in the product, a warning should be clearly labelled on the packaging and in the user guidance.	

Desirable

	✓ or X or N/A
• Stability and compatibility data should be available for injectable medicines commonly prepared as infusions in aseptic units. This should include: ▪ Physico chemical compatibility with common diluents (saline, glucose % etc) ▪ Physico chemical compatibility with common containers + packaging (polypropylene, glass, PVC etc) ▪ Route of chemical degradation ▪ Physico – chemical compatibility with other drugs ▪ Degradation rate ▪ Shelf life at 4°C + 25°C in recommended diluents ▪ Validation for use with mini-bag plus	
• Bio-availability data should be available for modified release preparations or medicines with a narrow therapeutic index to confirm that the product is comparable with the market leader.	

Risk categorisation

Critical (C), Major (M), Minor (0) or satisfactory (S)	

Any deficiencies in the essential criteria will lead to a critical or major risk rating for that section. Deficiencies in the desirable criteria will lead to a minor rating. Multiple failings in the desirable criteria may lead to a major rating.

7. Product Quality

Essential

	✓ or X or N/A
• Tablets and capsules in bulk containers should be marked for easy identification.	
• Scored tablets should be easily halved.	
• There should be no evidence of damage or lack of dose uniformity in tablets.	
• Pack closures should be tamper evident • Patient packs should have child resistant closures	
• Powders intended for dissolution should dissolve easily.	
• Suspensions and emulsions should re-suspend easily upon shaking.	
• Labels on vials/ampoules intended for use in aseptic units should be resistant to spraying and wiping with alcohol.	
• Vials intended for reconstitution must be of sufficient size to allow reconstitution with the volume of diluent commonly used in aseptic units (not just to allow bolus administration at ward level).	
• Cytotoxic vials/ampoules should be washed or coated following manufacture to minimise potential contamination.	

Desirable

	✓ or X or N/A
• Tablets /capsules in blister packs should be marked for easy identification.	
• Tablets /capsules in blister packs should be easily 'popped out' and the blister pack should have no sharp edges.	
• The taste of liquid formulations should be acceptable for all patient groups.	
• Oral liquid medicines should be sugar free.	

Risk categorisation

Critical (C), Major (M), Minor (0) or satisfactory (S)	

Any deficiencies in the essential criteria will lead to a critical or major risk rating for that section. Deficiencies in the desirable criteria will lead to a minor rating. Multiple failings in the desirable criteria may lead to a major rating.

8. Licensing

Essential

	✓ or X or N/A
• Licensed medicines must be licensed for use in the UK.	
• Unlicensed medicines must be risk assessed in accordance with the Trust policy for Unlicensed Medicines.	
• The licensed indications should be clearly stated on the SPC and PIL.	
• The licensed routes of administration should be clear and obvious.	
• The licensed indications and routes of administration should be comparable to the brand leader.	

Desirable

	✓ or X or N/A
• None	

Risk categorisation

Critical (C), Major (M), Minor (0) or satisfactory (S)	

Any deficiencies in the essential criteria will lead to a critical or major risk rating for that section. Deficiencies in the desirable criteria will lead to a minor rating. Multiple failings in the desirable criteria may lead to a major rating.

9. Robot Compatibility

Essential

	✓ or X or N/A
• The pack integrity, dimensions and layout should be compatible with the automated dispensing system.	
• A bar code should be present on the pack.	

Desirable

	✓ or X or N/A
• None	

Risk categorisation

Critical (C), Major (M), Minor (0) or satisfactory (S)	

Any deficiencies in the essential criteria will lead to a critical or major risk rating for that section. Deficiencies in the desirable criteria will lead to a minor rating. Multiple failings in the desirable criteria may lead to a major rating.

Purchasing for Safety

Appendix 2: Risk assessment results summary spreadsheet

Initials of person carrying out risk assessm	Date	Product Description	Pack size	Manufacturer	Critical Information	User Information	Pack Design	Corporate Livery	Dose administration	Technical data	Product quality	Licensing Issues	Robot compatibility	Overall Risk Rating	Comments