



## PURCHASING FOR SAFETY POLICY

Policy Type	Non Clinical
Directorate	Acute
Policy Owner	Chief Operating Officer Acute and Ambulance
Policy Author	Lead Pharmacist Technical Services and Oncology & Lead Technician Medicines Use and Safety Team
Next Author Review Date	1 <sup>st</sup> January 2022
Approving Body	Policy Management Sub-Committee 13 <sup>th</sup> June 2018
Version No.	2.0
Policy Valid from date	1 <sup>st</sup> June 2018
Policy Valid to date:	30 <sup>th</sup> June 2022

**‘During the COVID19 crisis, please read the policies in conjunction with any updates provided by National Guidance, which we are actively seeking to incorporate into policies through the Clinical Ethics Advisory Group and where necessary other relevant Oversight Groups’**

## DOCUMENT HISTORY

(Procedural document version numbering convention will follow the following format. Whole numbers for approved versions, e.g. 1.0, 2.0, 3.0 etc. With decimals being used to represent the current working draft version, e.g. 1.1, 1.2, 1.3, 1.4 etc. For example, when writing a procedural document for the first time – the initial draft will be version 0.1)

Date of Issue	Version No.	Date Approved	Director Responsible for Change	Nature of Change	Ratification / Approval
21 Feb 14	0.1		Executive Medical Director		
16 Oct 14	0.2		Executive Medical Director	Committee added to policy	Ratified at Hospital & Ambulance
16 Oct 14	0.2		Executive Medical Director	Committee added to policy	Ratified at Quality, Risk & Patient Safety Committee
24 Oct 14	0.3		Executive Medical Director		Ratified at Drugs Advisory Committee
09 Dec 14	0.4		Executive Medical Director		Ratified at Patient Safety, Effectiveness and Patient Experience (SEE)
06 Feb 15	0.4		Executive Medical Director		Ratified at Clinical Standards Group
17 Mar 15	0.4		Executive Medical Director		Ratified at Policy Management Group
23 Mar 15	1	23 Mar 15	Executive Medical Director		Approved at Trust Executive Committee
3 May 2018	1.1		Medical director		Ratified at Drugs Advisory committee
23/4/18	1.2		Medical Director	Review and Update	CBU Quality, Risk & Patient Safety Group
25/05/2018	1.2		Medical Director	To be ratified	Clinical Standards Group
13/06/2018	2.0	13 June 18	Medical Director	Approved at	Policy Management Sub-Committee
29/01/2021	2.0	13 June 18	Chief Operating Officer Acute & Ambulance	12 month blanket policy extension due to covid 19 applied with author review date set 6 months prior to Valid to Date.	Quality & Performance Committee
20/05/2021	2.0	13 June 18	Chief Operating Officer Acute & Ambulance	Extended policy uploaded and linked back with new cover sheet	Corporate Governance

NB This policy relates to the Isle of Wight NHS Trust hereafter referred to as the Trust.

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## 1. Executive Summary

The use of all medicines may not only incur a risk of an adverse drug reaction (ADR) but also of a clinical incident such as an inappropriate reconstitution or administration error. These types of medication error risks can and should be minimised by “Purchasing for Safety” in the first instance.

All NHS pharmacy staff assumes a duty of care when supplying a medicine. In order to reduce the number/frequency of incidents caused by medication errors it is essential that all risks are identified and assessed. Following risk identification and assessment action must be taken to minimise the possibility of a patient safety incident

Effective procurement of the right medicine is an important tool in the risk reduction process. This includes Pharmacists not only assessing a product's clinical effectiveness and ADR potential but also its safety in use when responding to a request for a new medicine. Medicines should only be purchased if they are of a suitable quality, safe to use and fit for purpose. Moreover it is essential that the procurement process assesses the capabilities of the supply chain to the hospital to ensure that products are genuine, have been correctly stored and are available when required.

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

Licensed medicines are procured wherever possible. Unlicensed medicines may only be used when no suitable licensed product is available to meet the special needs of an individual patient. .

## 2. Introduction

The use of all medicines involves the potential risk of an adverse event, but this risk can be minimised by ensuring safe methods of procurement. The NPSA (now NICE) recommended that all healthcare organisations implement a “purchasing for safety” policy to promote the procurement of injectable medicines with inherent safety features. In 2006 the NPSA issued a guide for the graphic design of medication packaging, followed in 2007 by a guide to the design of dispensed medicines ([www.npsa.nhs.uk](http://www.npsa.nhs.uk)).

## 3. Definitions

**CMU:** Commercial Medicines Unit. Part of the Department of Health responsible for National and Regional contracting for Medicines.

**Licensed medicine:** Medicinal product for human use, which has been determined by the MHRA to be industrially produced for marketing purposes, have required efficacy, reliability and quality for human use. Medicines legislation (specifically The Medicines for Human Use Regulations 1994/SI 3144) requires that medicinal products are licensed before they are marketed in the UK.

**MEPA :** Medication Error Potential Assessment. A risk score that reflects a product's suitability for use, based upon a wide number of factors e.g. clarity of labelling, packing, availability of patient information

**MHRA:** Medicines and Health Product Regulatory Agency. The UK government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe.

**NPSA:** National Patient Safety Agency (now incorporated into NICE)

**NICE-** National institute for Health and Care Excellence

**Off-label use:** Medicines with a UK Marketing Authorisation, which are prescribed for an indication, or route not included in the product license.

**PrOMS:** Potential Risk of Medication Selection- a system for reporting medicines with packaging that may cause confusion.

**QA:** Quality Assurance

**RDPC:** Regional Drug Purchasing Centre

**Unlicensed medicine:** A medicinal product not licensed for use with the UK by the MHRA; but may be used by individual patients on the direct personal responsibility of a doctor or dentist registered in the UK.

#### 4. **Scope**

This policy applies to all medicines procured for use by the Isle of Wight NHS Trust and all staff involved in medicines management, from the decision to procure to the point of administration. It also applies to medicines procured through third parties for direct delivery to patients' homes.

#### 5. **Purpose**

**The purpose of this policy is to ensure best procurement practice is followed when purchasing medicines to ensure safe, cost effective and timely provision of medication to patients. The policy outlines the process for managing medicines shortages as these also have implications for patient care**

#### 6. **Roles and responsibilities**

##### **Medical Director**

The Medical Director has delegated responsibility for ensuring safe prescribing practices are implemented, maintained and monitored.

##### **Chief Pharmacist**

The Chief Pharmacist has responsibility for ensuring processes are in place to support this policy.

##### **Clinical Pharmacists**

Pharmacists must ensure that the appropriate level of clinical / pharmaceutical scrutiny is carried out when presented with a request to supply a new drug.

### **Drugs Advisory Committee**

The committee is responsible for ensuring that safety considerations are taken into account for any new product requests.

### **Quality committee**

This group has responsibility for overseeing the delivery of the patient safety, agenda within the organisation.

### **Pharmacy Procurement Staff**

Pharmacy procurement staff are required to implement this policy, follow best procurement practise and ensure pharmacy staff follow relevant standard operating procedures (SOPs)

### **All Healthcare Professionals**

Each healthcare professional who prescribes, handles, supplies or administers medicines is accountable for working within current legislation, within the Code of Conduct of their professional body and complying with their professional guidance.

## **7. Policy detail/course of action**

- 7.1 All purchases for medicinal products will be made from trusted sources of supply to ensure the suitability of products purchased and minimise the possibility of counterfeit medicines.
- 7.2 Suppliers and wholesalers are required to hold an appropriate licence from the MHRA and this will be checked for authenticity by the pharmacy procurement staff. This includes homecare providers.
- 7.3 As many medicines as possible will be purchased under the Commercial Medicines Unit (CMU) contract. This means medicines have undergone a risk assessment process and received a medication error potential assessment score (MEPA).

For drugs purchased outside a CMU contract the Purchasing Safety Decision Tree must be followed (**Appendix B**)

NHS CMU holds a list of inspected suppliers who hold or have successfully held a CMU contract. This database (NHS SID) is held on their website. Pharmacy procurement specialists can give advice about potential new suppliers. It is important that the entire supply chain has been assessed

Any concerns with a supplier will be raised with CMU and if deemed necessary audit reports undertaken to access the supplier performance.

- 7.4 Safe and secure methods of procurement (e.g. e-procurement via Medecator) should be utilised wherever possible to minimise the potential for error during the process.
- 7.5 Where available, a medicine with a product licence issued by the MHRA, or a product licensed as medical device with a CE mark, should be used in preference. Exceptions may occur; for example if an unlicensed but ready-to-use formulation which reduces risk at the point of use is available from a reputable "specials" manufacturer.

Unlicensed medicines may be purchased to meet the special clinical need of an individual patient but, unlike licensed products, responsibility for their use lies with the Trust. They should only be obtained from a reliable source which is able to ensure the authenticity and security of the supply chain.

Where an unlicensed preparation is required then it should be procured following the Isle of Wight NHS Trust Unlicensed Medicines guidelines (section 7.8.of the [Trust Medicines Policy](#))

- 7.6 New products, including unlicensed manufactured products and unlicensed imports, should be entered on JAC by the Pharmacy IT Team upon receipt of an appropriately completed form to ensure that all products are described to the same standards.
- 7.7 Incidents involving the procurement or quality of medicines should be reported using the trust incident reporting system (DATIX)  
External reporting schemes for medicines errors, incidents and defects as outlined in Appendix C will be actioned where relevant by pharmacy staff.
- 7.8 Medicine shortages occur from time to time. These shortages can be for a number of reasons such as merger of pharmaceutical manufacturers, cost of licensing for new generic formulations, lack of raw material, or operational difficulties at the manufacturing plant. The Department of Health, CMU or the 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.

When there is notification of a problem with product supply, the flow chart for Managing Medicines Shortages should be followed (Appendix F)

- 7.9 Trust staff may not accept free samples of medicines from any supplier.  
The Chief Pharmacist may exceptionally authorise the use of free supplies of medicines when it is in the best interests of patients to do so. Such medicines will be received and distributed solely through the Pharmacy

## **8. Consultation**

The Purchasing for Safety (Medicines) policy has been written in light of recommendations by the NPSA (now NICE). This is a separate policy to the Medicines Policy but should be read in conjunction with it. The revised policy has been agreed with the Drugs Advisory Committee, The CBU Quality and Patient Safety, Experience & Clinical Effectiveness Group, the Clinical Standards Group and the Patient Safety Sub Committee

## **9. Training**

This purchasing for safety (medicines) policy does not have a mandatory training requirement.

Pharmacy staff including on call pharmacists, will receive documented training as needed depending on their role

## **10. Monitoring compliance and effectiveness**

Medication errors that relate to issues identified in this policy will be reviewed. This will occur continuously for individual incidents.

Compliance with the document will be monitored in the following ways.

Aspect of compliance or effectiveness being monitored	Monitoring method	Responsibility for monitoring	Frequency of monitoring	Group or Committee that will review the findings and monitor completion of any resulting action plan
Purchasing of unlicensed medicines	All unlicensed medicines are monitored following SOP. Details are recorded, filed and reviewed.	Lead Pharmacist Technical Services and Oncology	Continuous	N/A
Incidents relating to quality	Audit of incidents documented Datix	Medicines Use and Safety Team	Annual	DAC
Medicines ordered outside of contract	Contract variance report	Pharmacy Stores & Distribution Manager	6 monthly	

## 11. Links to other Organisation documents

- [Trust Medicines Policy](#)
- [Trust Standing financial Instructions](#)
- Representatives Policy (available via Procurement pages on the Intranet)
- [Homecare Medicines Services Policy](#)

## 12. References

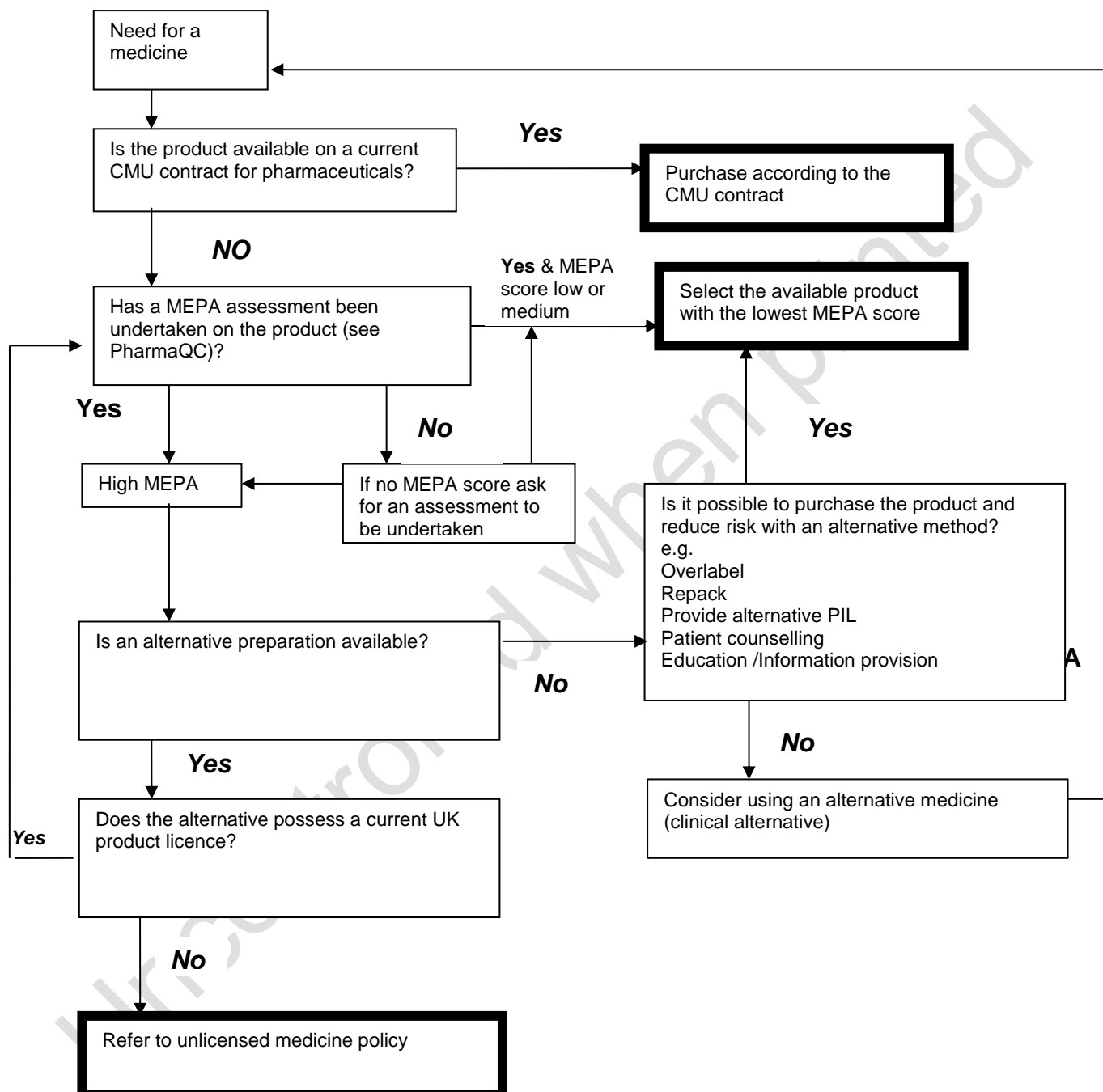
- NPSA Alert 20. Safer Practice with injectable medicines. 2007
- Safe and secure handling of medicines – a team approach RPS
- Commercial medicines unit <http://cmu.dh.gov.uk/>
- [MHRA How we regulate medicines](#)
- [MHRA adverse drug reaction guidance- Yellow Card Scheme](#)

## 13. Appendices



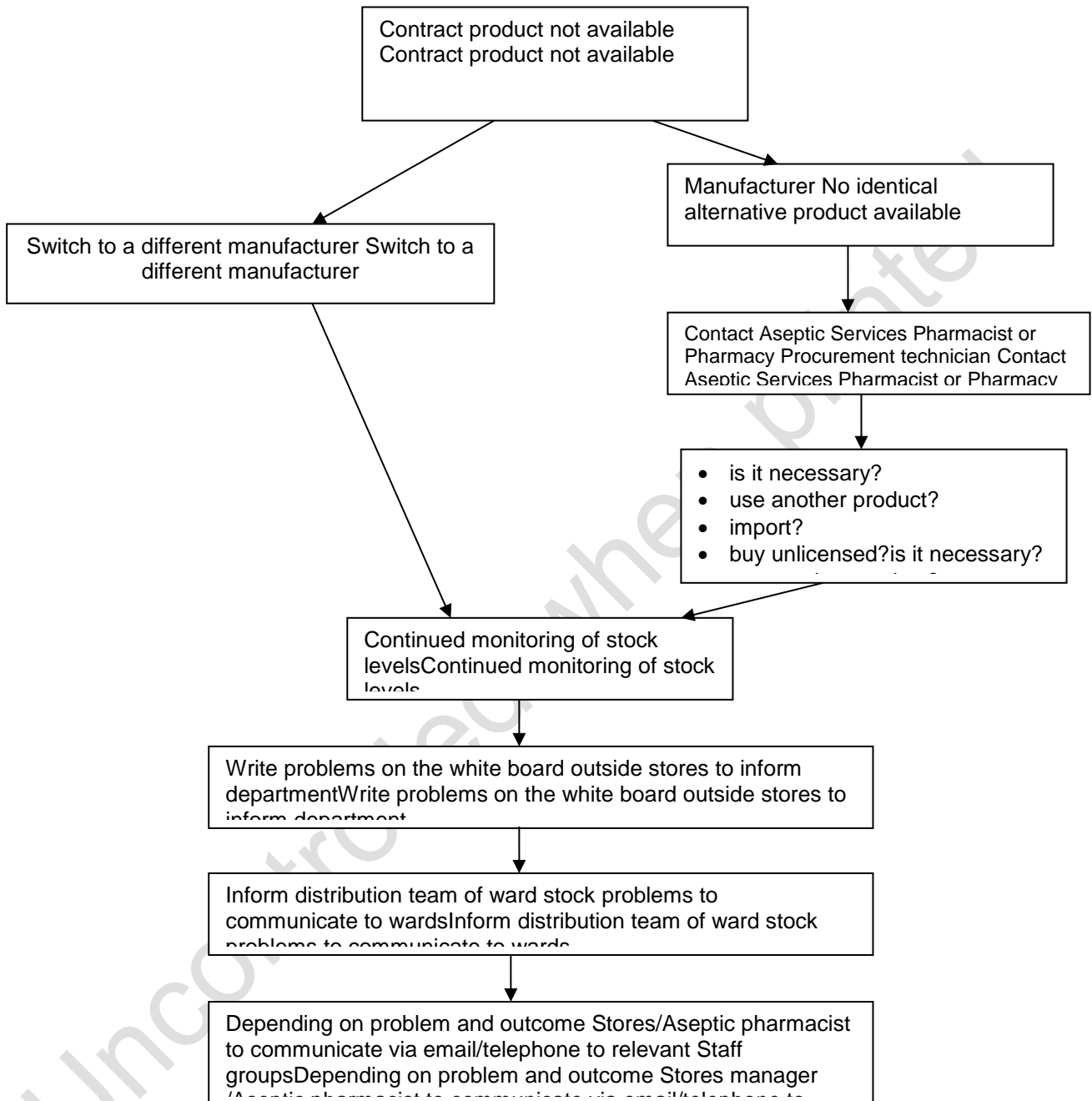
### Purchasing for Safety Decision Making Tree

This details the steps necessary to ensure the safety of medicines purchased for use in the Trust



**MEDICINE ERROR, INCIDENT AND DEFECT REPORTING SYSTEMS**  
**What systems are there and when to use them**

Reporting System	When to Use	Examples (not exhaustive list)	Report Sent To	Contact Information
MHRA Counterfeits Case Referral Centre	Suspected counterfeit product		MHRA Counterfeits Case Referral Centre	<b>Telephone:</b> 020 3080 6701 (24 hours)  Email: <a href="mailto:counterfeit@mhra.gsi.gov.uk">counterfeit@mhra.gsi.gov.uk</a> <a href="http://yellowcard.mhra.gov.uk/">http://yellowcard.mhra.gov.uk/</a>
MHRA Yellow Card (adverse reactions and defective medicines)	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	
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 <a href="mailto:pharmacyQAinfo@gstt.nhs.uk">pharmacyQAinfo@gstt.nhs.uk</a>
ProMS (Potential Risk of Medication 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. Manufacturers packaging has poor differentiation between different products or strengths.	Regional Quality Assurance Service (London and South East or Eastern)	Email to <a href="mailto:pharmacyQAinfo@gstt.nhs.uk">pharmacyQAinfo@gstt.nhs.uk</a>
CMU (Commercial Medicines Unit)	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. <a href="http://cmu.dh.gov.uk/">http://cmu.dh.gov.uk/</a>



## Financial and Resourcing Impact Assessment on Policy Implementation

*NB this form must be completed where the introduction of this policy will have either a positive or negative impact on resources. Therefore this form should not be completed where the resources are already deployed and the introduction of this policy will have no further resourcing impact.*

<b>Document title</b>	<b>Purchasing for Safety (Medicines) Policy</b>
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<b>Totals</b>	<b>WTE</b>	<b>Recurring £</b>	<b>Non-Recurring £</b>
Manpower Costs	0		
Training Staff	0		
Equipment & Provision of resources	0		

**Summary of Impact: Nil**

**Risk Management Issues: Nil**

**Benefits / Savings to the organisation:** ensures best value procurement of medicines

### Equality Impact Assessment

- Has this been appropriately carried out? YES
- Are there any reported equality issues? NO

If "YES" please specify:

**Use additional sheets if necessary.**

Please include all associated costs where an impact on implementing this policy has been considered. A checklist is included for guidance but is not comprehensive so please ensure you have thought through the impact on staffing, training and equipment carefully and that ALL aspects are covered.

<b>Manpower</b>	<b>WTE</b>	<b>Recurring £</b>	<b>Non-Recurring £</b>
Operational running costs			
<b>Totals:</b>			

<b>Staff Training Impact</b>	<b>Recurring £</b>	<b>Non-Recurring £</b>
<b>Totals:</b>		

<b>Equipment and Provision of Resources</b>	<b>Recurring £ *</b>	<b>Non-Recurring £ *</b>

Accommodation / facilities needed		
Building alterations (extensions/new)		
IT Hardware / software / licences		
Medical equipment		
Stationery / publicity		
Travel costs		
Utilities e.g. telephones		
Process change		
Rolling replacement of equipment		
Equipment maintenance		
Marketing – booklets/posters/handouts, etc.		
<b>Totals:</b>		

- Capital implications £5,000 with life expectancy of more than one year.

Funding /costs checked & agreed by finance:	
Signature & date of financial accountant:	
Funding / costs have been agreed and are in place:	
Signature of appropriate Executive or Associate Director:	



### Equality Impact Assessment (EIA) Screening Tool

Document Title:	Purchasing for Safety (Medicines) Policy
Purpose of document	to ensure best procurement practice is followed when purchasing medicines
Target Audience	<i>Clinical staff and managers</i>
Person or Committee undertaken the Equality Impact Assessment	<i>Liz Harrison, Deputy Chief Pharmacist</i>

1. To be completed and attached to all procedural/policy documents created within individual services.
2. Does the document have, or have the potential to deliver differential outcomes or affect in an adverse way any of the groups listed below?

If no confirm underneath in relevant section the data and/or research which provides evidence e.g. JSNA, Workforce Profile, Quality Improvement Framework, Commissioning Intentions, etc.

If yes please detail underneath in relevant section and provide priority rating and determine if full EIA is required.

		Positive Impact	Negative Impact	Reasons
<b>Gender</b>	Men	<i>no</i>	<i>no</i>	
	Women	<i>No</i>	<i>no</i>	
<b>Race</b>	Asian or Asian British People	<i>no</i>	<i>no</i>	
	Black or Black British People	<i>no</i>	<i>No</i>	
	Chinese people n0	<i>no</i>	<i>No</i>	
	People of Mixed Race	<i>no</i>	<i>No</i>	
	White people (including Irish people)	<i>no</i>	<i>no</i>	
	People with Physical Disabilities, Learning Disabilities or	<i>no</i>	<i>No</i>	

	Mental Health Issues			
<b>Sexual Orientation</b>	Transgender	<i>no</i>	<i>No</i>	
	Lesbian, Gay men and bisexual	<i>no</i>	<i>No</i>	
<b>Age</b>	Children	<i>no</i>	<i>No</i>	<i>Provision is made for the off license use of medicines including in children</i>
	Older People (60+)	<i>no</i>	<i>no</i>	
	Younger People (17 to 25 yrs.)	<i>no</i>	<i>No</i>	
<b>Faith Group</b>		<i>no</i>	<i>No</i>	
<b>Pregnancy &amp; Maternity</b>		<i>No</i>	<i>No</i>	
<b>Equal Opportunities and/or improved relations</b>		<i>No</i>	<i>No</i>	

Notes:

Faith groups cover a wide range of groupings, the most common of which are Buddhist, Christian, Hindus, Jews, Muslims and Sikhs. Consider faith categories individually and collectively when considering positive and negative impacts.

The categories used in the race section refer to those used in the 2001 Census. Consideration should be given to the specific communities within the broad categories such as Bangladeshi people and the needs of other communities that do not appear as separate categories in the Census, for example, Polish.

### 3. Level of Impact

If you have indicated that there is a negative impact, is that impact:			
		<b>YES</b>	<b>NO</b>
<b>Legal</b> (it is not discriminatory under anti-discriminatory law)			
<b>Intended</b>			

If the negative impact is possibly discriminatory and not intended and/or of high impact then please complete a thorough assessment after completing the rest of this form.

3.1 Could you minimise or remove any negative impact that is of low significance? Explain how below:	
3.2 Could you improve the strategy, function or policy positive impact? Explain how below:	
3.3 If there is no evidence that this strategy, function or policy promotes equality of opportunity or improves relations – could it be adapted so it does? How? If not why not?	
Scheduled for Full Impact Assessment	Date:

Name of persons/group completing the full assessment.	
Date Initial Screening completed	

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