3. PROCUREMENT/ACQUISITION OF MEDICINES

3.1. Purchasing For Safety

Introduction

Medicines must be procured to ensure that the right medicine is available in the right quantity and quality, at the right time for the right patient.

Responsibility for procurement of medicines in a hospital rests ultimately with the Chief Pharmacist. All medicines are procured by the hospital Pharmacy Department, although authority for certain specific products may be delegated elsewhere (e.g. medical gases, which may be purchased by Estates/Facilities or dialysis fluids which may be purchased by the renal supplies team).

In some healthcare areas medicines may be procured via an SLA. The following principles outline below would still be accepted to apply.

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. 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. 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. 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.

3.1.1. Risk Assessment

Risk assessments should be carried out where appropriate and need to be undertaken by staff with a full understanding of the purpose and end use of the product being procured.

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 (Pharmacy Quality Assurance) score which reflects suitability for use and potential for medication error. The assessments are available on the PharmaQC database. Similarly products on a regional contract will be risk assessed by the regional team when awarding the contract. Safety medication bulletins are produced and at UHL these are reviewed and any high/medium risks taken to the monthly Quality & Safety Board or equivalent for further discussion.

New medicines to the Trust go through the process of a risk assessment alongside the submission to the Therapeutic Advisory Service (TAS) and at the time of adding them to the pharmacy stock management system. There are additional risk assessments for all unlicensed preparations which must be assessed following the Trust's Policy for Unlicensed medicines; and for all new injectable products which require an NPSA (National Patient Safety Agency) risk assessment carried out by the relevant senior pharmacist requesting the product.

The results of the risk assessments are recorded centrally, any deemed as high risk are referred to the monthly Quality & Safety Board or equivalent for approval and also reported to the regional QA specialist. These can then form the basis of discussion with the manufacturers about possible changes in presentation.

3.1.2. Components of Safety

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Risk assessment 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

3.1.3. Quality Design and Labelling of Product

I. Licensed Products

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.

A risk assessment tool for use with injectable products and practices in clinical areas is available on SPS (Specialist Pharmacy Services) web pages under a section on archived NPSA (National Patient Safety Agency) alerts, specifically promoting safe use of injections medicines NPSA 20 [1]. The results of the risk assessment will help to identify high risk injectable products that require having their risks managed in practice. 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. 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.

II. Assessed Products

Before a product is included onto a NHSE contract it is assessed by NHS Pharmacy QA staff according to an assessment tool developed by the National NHS QA Committee and scored according to its suitability for use and likelihood to cause a medication error. (For example the clarity of the labelling, the suitability for use, the availability of patient information etc.) The assessment tool can be obtained from your regional QA pharmacist. Assessed products present a known risk and should be used in preference to those not assessed (and consequently presenting an unknown risk). Thus purchasing off contract should only be undertaken with caution and risk assessment.

Source of Products

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 minimised. Suppliers and wholesalers are required to hold an appropriate licence from the MHRA and this should be checked for authenticity. NHSE holds a list of suppliers who hold or have successfully held a NHSE contract. Pharmacy QA and procurement staff inspect potential pharmaceutical

[1] National Patient Safety Agency. Alert 20. Safer Practice with injectable medicines. 2007. www.sps.nhs.uk

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suppliers and these reports can be used to assess new suppliers. 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.

NHSE (and others) undertake supplier performance measurement and award where possible to those suppliers who have a better supply record. This reduced supply risk is obviously a component for patient safety.

Safe and secure methods of procurement (e.g. e-procurement) should be utilised to minimise the potential for error during the process.

III. "Ready-to-Use"/ "Ready to Administer"

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

Medicines which represent the minimum risk throughout the whole of this process should be preferred. Where possible higher risk products should be prepared (e.g. reconstituted) either in house by the Pharmacy Aseptic Unit or by commissioning a (licensed and suitable) manufacturer to prepare the medicine in a suitable format to minimise the risk.

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

3.2 Procedure for Procurement

3.2.1 Demand

- Identification of demand for a particular medicine will occur as medicines are prescribed and issued from pharmacy stock
- A medicine may only be purchased if it has been approved for use within the Trust i.e. it is included in the Leicestershire Medicines Formulary or for specialist use. One off purchases may be made for continuation of treatment if alteration to therapy is felt to be inappropriate. In UHL the approval of both the Therapeutic Advisory Service (TAS) and the funding CMG are required. For Free of Charge and expanded access schemes, local policies and RMOC (Regional Medicines Optimisation Committee) guidance relating to this should be referred to.

3.2.2 Reorder Level and Quantity

- Medicines which are routinely stocked by the pharmacy department will be re-ordered in accordance with the stock control parameters that have been set for that item on the pharmacy computer system. These will determine when the item is re-ordered and what quantity will be bought. Automated stock control parameters should be used whenever possible to ensure that reorder levels and quantities are based on product usage. For very slow moving or very bulky items, it may be necessary to resort to manual stock control.
- Non-formulary medicines will not normally be included on automated stock control unless there are specific risks to the patient of not having the medication available e.g. anticonvulsants

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3.2.3 Choice of Supplier

- The majority of the medicines used are put out to tender by the NHSE. Contracts are awarded at national, regional or procurement hub/consortium level to suppliers, for supply to the NHS. The contracted supplier should always be used as this represents best value to the NHS. Buying off contract for pricing benefit on a single line risks undermining the wider purchasing process.
- Where no contract is in place for supply of a particular medicine, it should be purchased from a pharmaceutical wholesaler (in accordance with the terms of local trust wholesaler contracts) unless it is available at a lower price directly from the manufacturer.
- If the contracted supplier is unable to supply the medicine in time to meet the clinical needs of patients, an alternative source of supply may be used. A claim for reimbursement of extra costs incurred may be made against the contracted supplier, under the NHS Terms and Conditions of Contract.

3.2.4 Ordering

- Ordering of medicines is carried out by the Pharmacy Purchasing Office (during office hours)
- Orders for medicines should be transmitted to suppliers electronically wherever possible to reduce the risk of errors
- Out of hours, in cases of emergency, where a medicine is required that is not available in the Pharmacy Department, the Duty Pharmacist may order the medicine from a wholesaler or another hospital or other usual supplier. In this case, the order will be placed by telephone and the details passed to the Pharmacy Purchasing Office on the next working day.

3.2.5 Unlicensed Medicines

- Unlicensed medicines should be procured in accordance with the Unlicensed Medicines Policy
- The Pharmacy Department is responsible for the specification of an unlicensed medicine, and with ensuring that the product supplied meets the specification and is of acceptable quality

3.2.6 Home Delivered Medicines via the Pharmacy Homecare Service

- All supplies of home delivered medicines should be ordered in conjunction with the Pharmacy Department
- The prescription for a home delivered medicine constitutes the order and this should, whenever possible be professionally checked by a pharmacist

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