

Purchasing safer medicines

— a national risk assessment strategy

By **Andrew Alldred**, BPharm, MRPharmS

NHS purchasing groups can help reduce medicine-related errors by ensuring that the medicines they purchase have been assessed for their error potential. This article describes factors involved in the risk assessment process



Drug contracts should be awarded on the basis of risk rating, not just cost

Since the introduction of clinical governance in the NHS, adverse health care events have become a major focal point for health care professionals. The UK Government is focusing on improving the quality of care and patient safety within our health care system and have published several policy documents to this effect.¹⁻³

“An organisation with a memory” identified four categories of serious recurring adverse events and developed national targets for action in these areas.¹ Two of these targets involved medicine use:

- To reduce the number of serious errors in the use of prescribed drugs by 40 per cent by 2005
- To reduce death or paralysis caused by maladministered spinal injections to zero by the end of 2001

The NHS and, in particular, the pharmacy profession are currently focusing attention on reducing serious errors associated with medicines use. Over the past few years attention has been focused on the labelling and packaging of medicines and the role these play in ensuring safe medicine use.³⁻⁵ There are many reports detailing the influence that labelling and packaging has on dispensing

errors, reported anecdotally, through root cause analysis and in formal error reporting by trusts.^{6,7}

In April 2002, the Committee on Safety of Medicines established a working group in response to the high profile death of a teenager in the UK, following a spinal injection of vincristine. The remit of the group was to review the labelling and packaging of medicines, in particular that of the vinca alkaloids, to see what improvements could be made. The findings were published in “MLX 275 — recommendations for the labelling and packaging of medicines”, and were widely consulted on.⁴

As a direct response to this consultation, the Medicine and Healthcare products Regulatory Agency, in conjunction with the National Patient Safety Agency and the Association of the British Pharmaceutical Industry, developed its “best practice guidance on the labelling and packaging of medicines”.³ Although this was a welcome step forward, it stopped short of implementing all the recommendations outlined in MLX 275. It is worth noting that although the guidance has no legal standing (legislative requirements for labelling are set out in European Directives), its recommendations are taken into account when the MHRA assesses the labelling provided with licence applications.

More recently the Department of Health has published “Building a safer NHS for patients — improving medication

safety” (January 2004).³ This document has specific recommendations for NHS purchasing groups and the pharmaceutical industry to help improve safe use of medicines.

— Purchasing for safety

In 2001-02, while the Government was developing its safety policies, two purchasing groups (the Yorkshire Purchasing Consortium and the North West England Purchasing Consortium) started to develop a risk management strategy for purchasing medicines in England. They began this work independently in the first instance, and then collaboratively with the support of the National Patient Safety Agency. The purchasing groups identified the need to develop a national, standardised approach to risk assessment, building on regional quality control systems that were mainly focused on product testing. The aims of developing such an approach are outlined in Panel 1 (p18).

This led to the concept of a national “purchasing for safety” strategy, initially designed for secondary care, with the intention that it could later be rolled out across primary care. The strategy principally involves learning from medication errors that are, or may be, associated with labelling and packaging, and developing risk management criteria that may be used during the purchasing process.

The old “black on yellow” labelling standard for injections, one that has been

Andrew Alldred is director of pharmacy at Harrogate and District NHS Foundation Trust

recognised for many years by NHS Pharmaceutical Services, is no longer considered appropriate. The misidentification potential with this labelling standard was mentioned in the 2001 DoH report "Building a safer NHS for patients".² This standard has now been withdrawn and the industry is expected to conform to the requirements laid out in the MHRA best practice guidance.

Since 2003, the NHS Purchasing and Supply Agency has been working with the NPSA, the MHRA and NHS hospital pharmaceutical services, their quality controllers, and their suppliers to reflect this new guidance through its contracting arrangements for the supply of pharmaceuticals to NHS trusts in England.

— Risk assessment

The purchasing groups developed a risk assessment tool to aid the assessment of products at the purchasing stage. The "medication error potential risk assessment framework" was designed to be used as part of the contract adjudication process, and to provide feedback to NHS purchasing groups and the pharmaceutical industry. It was subsequently adapted by the NHS Pharmaceutical Quality Assurance Committee and published in 2004.⁸ The framework includes domains covered by MLX 275 and the MHRA best practice guidance.

The purpose of the risk assessment process is to identify and highlight particulars of a medicine that may give rise to an increased risk of a medication error, to ensure the medicine is fit for purpose and to ensure that the manufacturer's performance record is satisfactory. The aim of the

Panel 1: Aims of a national approach to risk assessment

- To learn from errors associated with medicines and to contribute to the reduction of medication errors related to adverse events as highlighted in "An organisation with a memory".
- To use the risk assessment criteria to ensure products with apparent inherent risk are not awarded a contract and to reduce the number of errors associated with critical products.
- To reduce the number of reports of injectable products that are incompatible with trust aseptic production services.
- To use the risk assessment criteria to hold informed discussion with the pharmaceutical industry about the importance of labelling and packaging in reducing medication errors.
- To analyse the financial impact of basing the decision making process on a risk assessment approach and to share the strategy with UK procurement colleagues.

risk assessment tool is to provide guidance on when to obtain samples or further information before purchasing a licensed medicine. Examples of the criteria for selecting product samples to assess are shown in Panel 2. The document also provides guidance on the process to be followed when considering the risks involved in purchasing a licensed medicinal product from a manufacturer.

The overall aim is to ensure that products with apparent inherent risk are not purchased. The assessment process therefore consists of three parts:

- The medicine's error potential in use
- The medicine's quality and fitness for purpose to ensure safe and secure handling
- The performance of the manufacturer

The risk assessment identifies the areas of risk associated with the medicine's labelling and packaging that form part of the procurement decision-making process. The factors considered as part of the risk

assessment process are outlined in Panel 3 (p19).

The risk assessment is designed both to evaluate the individual medicines and corporate livery issues (eg, drug form and strength differentiation) and to take into account the livery differentiation issues between different suppliers and manufacturers.

During the risk assessment process an overall risk rating is allocated to each product, categorised as high, medium or low. If any single risk category is deemed to be critical or high risk, the product is automatically assigned a high overall risk rating. Critical or high risk is defined as a single factor that, on its own, significantly contributes towards a high medication error potential in its use. In this case, a specific risk reduction measure would have to be implemented before general use (eg, caution in use and local risk assessment). The overall risk rating should take into account individual high risk factors, the overall assessment and evidence of errors in practice.

The overall risk for each product is reported to the contracting team. Purchasing

Panel 2: Situations in which products would undergo risk assessment as part of the procurement process

- Manufacturers unknown to the contracting team, or manufacturers new to a contract. Manufacturer with a poor history for a particular product or a poor history in general.
- New generic product.
- Change of contract to a new or different manufacturer where the product is known or suspected to be associated with problems.
- Products where obtaining technical information from the company may be considered necessary, eg, modified release formulations and products with a narrow therapeutic index where a change to the contract supplier or manufacturer is being considered.
- Products which do not have the same licence indications as a previous contract manufacturer's product.
- Products where samples may be required for assessment of labelling, packaging and presentation.
- Suppliers unknown to the contracting team or new to a contract.
- Products which are parallel imports, patient packs, accident and emergency packs, or ward packs not previously on a contract.
- Injections and irrigations, where there is a change in the contract supplier or nature of the container.
- Injections that require specialised labelling eg, potassium containing products, concentrated solutions for injection, intrathecal products.
- Products which are novel presentations eg, multi-chamber bags, pre-filled syringes.
- Products considered high risk eg, injectable products used in critical care areas requiring managed introduction.
- Products of a high risk therapeutic category eg, anticoagulants, critical care and resuscitation drugs, anaesthetics and anticonvulsants.
- Products used in aseptic units or pharmacy manufacturing units eg, cytotoxic agents.
- Products under review by the National Patient Safety Agency and associated with medication errors.
- Products associated with medication errors highlighted by trust-trend analysis or from medication-error-reporting databases.
- Products likely to be stored adjacent to one another in the pharmacy or clinical areas, from the same supplier, that have similar packaging and have been associated with error.
- Products with similar sounding names, similar spellings or products that are often implicated in medication errors.

decisions are then made on the basis of the risk rating and evidence of errors in practice. Wherever possible, products with a high or medium risk rating are not awarded contracts. Where it is necessary to purchase a medicine with a medium or high risk, local arrangements are in place to inform users of the risks involved. An important part of the process is communicating the findings to the MHRA, NPSA and to the manufacturer in order to allow labelling and packaging improvements to be made.

As a direct result of the roll out of the risk assessment process, the NHS has identified key parameters (other than cost) in the awarding of drug contracts in order to help reduce errors. In many circumstances using the risk assessment tool has resulted in contracts not being awarded to the products with the lowest price. The financial consequences of such decisions are small in comparison with overall medicine expenditure.

In practice the risk assessment process has been standardised and incorporated into the medicines procurement process within secondary care NHS in the UK. The assessment now forms a major component of the selection criteria used in the adjudication of secondary care medicine contracts.

In 2004 the process was successfully incorporated into the national Supply Chain Excellence Programme (SCEP) for awarding national secondary care medicine contracts for the NHS. A joint national quality control and procurement team was established to oversee the implementation of the framework into the SCEP. The risk assessment rating of products submitted for consideration of contract award are used in the adjudication meetings.

The assessment results of medicines considered for purchasing contracts are expected to be made available throughout the NHS via the Purchasing and Supply Agency Pharma QC database.

Conclusion

The purchasing for safety strategy within secondary care NHS has developed over the past two to three years. The risk assessment and quality assurance framework, used as part of medicine contract adjudication, has now been successfully implemented into local, regional and national procurement processes.

In the main, the pharmaceutical industry has reacted positively to the strategy, although progress was initially slow. Many companies were, and to some extent still are, sceptical about the role labelling and packaging plays in medicine errors, despite overwhelming evidence from root cause analysis. The generic pharmaceutical industry has been particularly responsive and many companies are proactively changing their packaging.⁹ The branded pharmaceuti-

Panel 3: Example domains of the risk assessment tool used to assess the error potential of products⁸

The error potential of the following situations is considered as part of the risk assessment process:

- Confusing the medicine with another product due to poor labelling or packaging:
 - Is the critical information in a large font on at least one side?
 - Is the generic name and strength on at least three non-opposing sides of the pack?
 - Is due prominence is given to the international non-proprietary name?
- Confusing the medicine with another due to similarity of the manufacturer's packaging across its product range:
 - Is there good differentiation between different medicines within the corporate livery of the company?
 - Is there good differentiation between strengths within the product range?
 - Is there good differentiation between dosage forms within product range?
- Confusing the medicine with another product when it has been removed from its outer packaging.
- Unknowingly using a medicine outside its licensed indications:
 - Are the licensed indications clearly stated on the summary of product characteristics, patient information leaflet or packaging?
 - Are the licensed routes of administration clear and obvious?
 - Are the licensed indications and routes of administration the same as the previously contracted item?
- Providing the incorrect dose due to complex manipulation before administration:
 - Is reconstitution required before use?
 - Does the product come with its own diluent?
 - Are serial dilutions required before use?
 - Are calculations required to determine the dose?
- Providing the incorrect dose due to poor or insufficient technical data.

cal industry, however, has been much slower to respond, in part due to global marketing conflicts and requirements to maintain corporate identity. This is despite the support of the ABPI.

It is clear from various sources and the authors in this series of articles that there is more to be achieved.^{6,9} The best practice principles have not been universally adopted and there continue to be risks associated with the labelling and packaging of medicines. The roll out of the strategy into primary care is particularly important. Since the current framework would need adaptation, the principles behind purchasing safe medicines for patients and using risk assessment criteria to make purchasing decisions should be examined carefully in this sector. There are challenges with this agenda in primary care, not least around the reimbursement of pharmacy contractors through the Drug Tariff. The new community pharmacy contract may go some way to alleviating some of these risks.

The development of the national Pharma QC database will facilitate the sharing of risk assessment ratings for licensed products, including digital images, across the UK and the sharing of such data with pharmacy contractors should be examined.

The strategy is still in its relative infancy but there is evidence of change, internal and external, to the NHS. It is now time for all key stakeholders to collaborate further to

reduce the potential for errors associated with medicines use.

References

1. Department of Health. An organisation with a memory. Report of an expert group on learning from adverse events in the NHS chaired by the chief medical officer. The Stationery Office. London. 2000.
2. Department of Health. Building a safer NHS for patients — implementing an organisation with a memory. The Stationery Office. London. 2001.
3. Department of Health. Building a safer NHS for patients — improving medication safety. The Stationery Office. London. January 2004.
4. Department of Health. Medicines Control Agency. consultation letter: MLX 275 — recommendations for the labelling and packaging of medicines, August 2001.
5. Department of Health. Medicines Control Agency: Best practice guidance on the labelling and packaging of medicines, March 2003.
6. Jenkins D, Gokani R. Dispensing errors — the impact of packaging. *Hospital Pharmacist* 2005;12:386.
7. Wang LN. How designer pharmacy could provide the answers to patient safety issues. *Pharmaceutical Journal* 2005; 275:507–08.
8. NHS Pharmaceutical Quality Assurance Committee. Quality assurance and risk assessment of licensed medicines for the NHS. 1st Edition, 2004.
9. Gross Z. Packaging and Labelling — The industry's role in patient safety. *Hospital pharmacist* 2005;12: 48–50.