

MANAGEMENT FORUM

# Patient safety will start with purchasing

*How packaging and labelling of medicines could be changed to improve patient safety was discussed at a meeting organised by Management Forum Ltd in London on 1 July. Jonathan Buisson reports*

In the near future, the process of improving patient safety in the National Health Service will begin at the point when medicines are purchased for use in the NHS, Professor DAVID COUSINS, head of safe medication practices at the National Patient Safety Agency, told the meeting.

Professor Cousins said: "Purchasing will take safety into account and not just price." The use of best practice guidance on packaging and labelling, launched earlier this year by the Medicines and Healthcare products Regulatory Agency, is to be incorporated into standard NHS contract specifications.

Purchasing pharmacists will also be asked to consider how individual products fit into the range of products produced by each supplier. "If they are all very similar and confusion could arise, then we are saying that they should not buy them." One thing which makes packs look similar is having a large manufacturer's logo on them. "Since the purchasing decision has already been made by the time the products reach the pharmacy shelf, I wonder why the logo is there. The patients do not really need to know who made their medicine."

Professor Cousins said that the NPSA is to launch a national reporting and learning system for the NHS in the autumn. "We will be looking at patient safety incidents — incidents which have, or could have, led to patient harm." This will start in secondary care, where error reporting systems have already been established. It will be extended first to primary care and then to patients and carers. Both prescription and non-prescription medicines will be covered by the system. Professor Cousins emphasised that the existing yellow card scheme for adverse drug reactions will continue. "Not all ADRs are medication errors," he said.

If the reporting system is to work properly the number of reports made will have to increase, Professor Cousin said. Over the



*Similarity of packaging can cause medication errors*

past 10 years the airline industry has seen the number of reports to its safety systems increase but the proportion of these that involve serious incidents has fallen. If this is to happen in health care then staff will have to have confidence that things will change as a result of any reports they make.

## LABELLING FOR SAFETY

JAN MacDONALD, head of product information, MHRA, said that although the labelling of pharmaceuticals is strictly controlled by European and United Kingdom legislation, "medicines labelling can be improved, even within this," she said.

The MHRA introduced new guidance on medicines labelling earlier this year (P7, 8 March, p321). Ms MacDonald said that while the guidance only applies to medicines licensed by the MHRA for use in the UK, it is being studied by the European Medicines Evaluation Agency. The guidance aims to have all the critical information necessary for using the medicine, including its brand and common names, strength,

form and route of administration and point-of-use warnings, gathered in one place. Pack designs, particularly for ranges of products from the same manufacturer, should make judicious use of contrasting colours for different strengths and alphabetically similar names.

In implementing its guidance, the MHRA is targeting particular products. Vinca alkaloids, methotrexate and high-strength potassium injections have already been addressed. Opiates and penicillins, often involved in medication errors, are to be looked at next. In addition, company rebranding exercises for their product ranges are being examined.

"Better labelling will not solve all of the problems with medication errors, but it will help to make medicines management safer." As well as taking packaging into account when making purchasing decisions, purchasing pharmacists need to make health care staff who are handling medicines, particularly at ward level, aware of any changes to packaging or labelling that occur as a result of their decisions.

In response to a question about how large the common name of a product should be printed in relation to the brand name, Ms MacDonald said that for a non-prescription product the common name should be at least as large as any straplines (such as those claiming "powerful pain relief") on the front of the package. For prescription medicines, where there is often a lot of white space on the pack, "we can see no reason why the common name should not be as large as the brand name".

## BETTER PATIENT INFORMATION

DAVID DICKINSON, director of consumer information and research consultants Consumption, said that in Europe 60–70 per cent of patients reported that they read, or tried to read, patient information leaflets. Interviews with patients showed that they had a sophisticated understanding of how medicines are used. "But better documents would be better read," he said (see Panel).

He said that PILs need to give medicine users a clear map of the information they contained.

One suggestion Mr Dickinson made was that as well as the main PIL, medicine packs should also include a credit card sized "summary of the summary" of the information, even if this was bending existing rules. This aide-memoire would contain only basic information on how to take the medicine and what to do about the main side effects. "Perhaps patients will keep this reminder, if nothing else," he said.

## Writing better patient information leaflets

Writing a patient information leaflet (PIL) should be an integral part of the development of a new pharmaceutical product and not an afterthought, according to NEIL EDWARDS, senior regulatory affairs consultant, PAREXEL International.

"A good PIL should send a message to the patient — this leaflet is important, it is for you and about you." The challenge is to translate the summary of product characteristics into everyday language and to think of the end user while meeting regulatory needs.

Readability testing with panels of prospective users is an important part of developing a PIL. Mr Edwards said that in projects he ran, problems were often found in the areas of contraindications, drug interactions, side effects and what to do about forgotten doses. A requirement for consultation with patient groups about leaflets is likely to be introduced by an ongoing revision of European pharmaceutical law.