

Packaging and labelling

— the industry's role in patient safety

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Clearer packaging and labelling of medicines helps minimise the risk of selection errors. This article examines some pharmacists' views on how the industry can help and looks at examples from companies who have taken steps to improve the packaging of their products



Medicines are often densely stored on dispensary shelves

Although there is no substitute for reading the label, improving the clarity of medicines packaging and labelling assists health care professionals, as well as patients and their carers, to select the correct medicine and use it safely.

Following publication of the document "Building a safer NHS for patients — implementing an organisation with a memory" in 2001, a number of recommendations were made by a working group of the Committee on Safety of Medicines to help improve medication labelling and packaging clarity (see Panel 1).^{1,2}

In 2003, best practice guidance was published by the Medicines and Healthcare products Regulatory Agency to expand on the principles set out by the CSM.³ In addition, other organisations such as the National Patient Safety Agency and the Association of the British Pharmaceutical Industry, have been instrumental in working towards safer handling of medicines. However, despite considerable efforts made by the industry itself to reduce the number of labelling and packaging associated medication errors, in practice, problems still exist.

This article looks at examples from three pharmaceutical companies that have

redesigned their labelling and packaging to try to ensure safer handling of medicines. It also addresses what pharmacists think the industry could or should do to improve medication safety.

— Packaging issues

So what do pharmacists think the industry could or should do to improve the packaging and labelling of medicines?

According to Stephen Athey, chief pharmacist, York Hospitals NHS Trust, the industry needs to focus on understanding how medicines are used in practice by health care workers and to design safe products and packaging that are fit for purpose. One of the many issues that needs addressing is that although hospitals are moving towards keeping patients' own medicines by the bedside, nursing staff still use the traditional drug trolley. With original pack dispensing there is a potential for nurses to select the wrong strength or formulation, he says.

Sequentially diluting or preparing a drug from multiple containers can also potentially lead to errors on wards and this is something that drug companies could help with to improve patient safety. Mr Athey says: "By and large we are looking for a product that is ready to administer or as close to ready to administer as possible." However, according to medicines safety pharmacist, Clare Crow-

ley, Oxford Radcliffe Hospitals NHS Trust, although ready diluted preparations would be useful for some products, in some cases "stability issues may prevent this from happening."

Miss Crowley raised the need for pharmaceutical companies to ensure that package inserts with injectable products contain information on preparation and administration. "This is a particular issue with generic products," she says. She points out that it would also be helpful if similar information was included for routine injectable specials. Manufacturers need to think practically and holistically, she says. Pharmaceutical companies need to think both in terms of how the required drug dose is given to the patient and how to ensure that the drug is delivered as easily as possible so that optimal treatment is received in a timely manner. She suggests that if a drug, for example, requires a filter for administration, then it would be a good idea for the manufacturer to include the filter with the drug as part of the kit.

Another area for improvement is blister packs. Commenting on this, Allan Karr, pharmacy business services manager, University College London Hospitals NHS Foundation Trust, says that it would be useful for all blister strips to be annotated above each individual sealed blister unit to enable identification of those tablets that have not yet been removed.

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— Labelling issues

Mr Karr addressed the issue of corporate designs on packaging. He says: "Drug companies have improved packaging by making labels easier to read. However, the use of corporate designs and colour differentiation is still causing medication errors to occur in practice as products continue to look the same. This is a particular problem for suppliers who have a large portfolio of products on the market."

Even though some drug companies are adhering to the recommendations made by the CSM, there are packs where the generic name needs to be made larger than the trade name and where one strength of a product needs to be easily distinguishable from another, Mr Athey points out. He adds that storage requirements, expiry dates and possibly other cautionary wording also need more prominence.

There is also a need for the industry to think about how prescriptions are written, and express the approved names and dose units on labels in a manner which is likely to correspond with that on the prescription. For example, prescribers most commonly use milligrams rather than expressing the strength as a percentage.

Labelling of multiple strength injectable drugs is another area for concern. Mr Athey comments that drug administration errors may occur because for some drugs the precise parenteral route for a particular strength may not be specified on the pack. For example, there may need to be a distinction on the labelling between IV bolus and IV infusion which is appropriate to the strength of the drug in the pack.

Another labelling issue that was raised was that small ampoules, such as 1ml and 2ml ampoules, often have font sizes that are too small to be read easily.

— Cost implications

Mr Karr suggests one way of improving the safe handling of medicines in the future is to have barcodes on packaging that not only contain product and supply details but also batch numbers and expiry dates. However,



Figure 1: Hameln Pharmaceutical's new packaging

Panel 1: Recommendations made by the CSM for labelling and packaging of medicines²

- Drug information for patients should include:
 - Name of drug, including generic name, in at least the same font size
 - Pharmaceutical form
 - Strength
 - Dosage
 - Warnings
- Critical information should be presented in the largest font size possible, and not obscured by logos or other markings.
- Generic name and strength should appear on at least three non-opposing faces of a carton and printed as black text on a white background.
- Innovative pack design across manufacturers' product ranges should ensure accurate identification of the drug rather than corporate recognition. Judicious use of colour to differentiate products in a range is encouraged.
- Where similarities exist between different drug names, pack design should be such that differences are easily discernible. Different fonts/text size should be considered.
- Blister foils should be printed to ensure maximum legibility of statutory information. Black text and central orientation of critical information is to be preferred. The generic drug name should appear on each blister pocket if size permits.
- Statutory warnings and cautionary and advisory labelling should be reviewed with patients to ascertain the most accessible means of presenting and wording information.
- Expiry dates and batch numbers should be printed in black on white for clarity. Embossing should not be used. Expiry dates stated in an unambiguous format. "Use before", followed by month and year of expiry are considered to give greatest clarity.
- Manufacturers packs should, where possible, include a blank white space (70mm by 35mm) in which there is no text of any kind for placement of the dispensing label. Any special storage instructions directed at the patient should be placed adjacent to this area.
- New or changes to packaging and labelling should be subject to a user test to ensure maximum clarity of the critical information.

any packaging and labelling developments, such as the introduction of bar codes on products, could mean that the production process would need to be altered and may incur additional costs to suppliers and subsequently to their customers.

It will be of no surprise if the introduction of new packaging and labelling comes with an increase in drug costs over the coming years. Mr Karr points out that drug companies "recognise that there are opportunities to differentiate their products from competitors by developing more patient safety orientated packs". However, the NHS is going to have to decide how much it is prepared to pay for purchasing these safer products. In doing so "decision makers will need to carefully weigh up the risks of a medication error occurring verses any additional cost," Mr Karr says.

— Redesign in practice

So much for the theory — what is the industry doing in practice? Over the past few years, some innovative pharmaceutical companies have moved towards new labelling and packaging designs for their products in response to the new safety agenda and clinical governance. Their efforts will help improve the safe handling of medicines by health care workers, patients and their carers.

Following are three examples of pharmaceutical companies that have been updating the packaging and labelling of their products: Hameln Pharmaceuticals, Alpharma and Mayne Pharma.

Hameln Pharmaceuticals introduced a new labelling and packaging design to its range of generic injectables in October last year. The company spent 16 months before that working on the redesign alongside a focus group of experts in the area of the safe use of medicines and packaging-induced medical errors.

The group recommended that the company perform a risk assessment that was not only product-specific but also took into account other Hameln products as well as other manufacturers' products, including products likely to be stored in the same area. As part of the risk assessment, poor practice, such as removing ampoules from their outer packaging, was taken into account. NHS hospital pharmacists were involved in reviewing the outcomes of the assessment and it was decided that a colour differentiation strategy, based on syringe labelling guidelines produced by the Association of Anaesthetists, would be adopted for the new design.

A number of changes were made to product labelling, and ampoule labelling was redesigned to match the labelling on the



Figure 2: new digoxin packs from Alpharma

outer carton to minimise risk of identification error. An example of Hameln's new packaging is shown in Figure 1 (p449).

Formal user testing, based on a picking test, was carried out in five hospital pharmacy departments, involving 105 pharmacy staff, to assess clarity and comprehension of the new labelling design compared with the company's previous packaging. The user test was repeated under different conditions, such as in poor lighting. Analysis of the results showed a shorter picking time with the new design.

— Colour and Braille

Following a global redesign of its packaging two and a half years ago and as part of its "accessible medicine programme", Alpharma says that it is continually evaluating the needs of pharmacists and patients. All feedback is assessed and, where necessary, improvements are made to packaging and labelling design. This is in addition to the company's adoption of new EU guidelines, where examples include adherence to, and exceeding, the guideline recommending a text size of seven points, addressing pack differentiation issues through the use of colour, introducing Braille labelling and conducting user-testing to assess readability.

Alpharma says that it has recently responded to a concern raised by a hospital pharmacist that there could be confusion among packs of its three strengths of digoxin tablets, which is a particular problem as it is a narrow therapeutic index drug. The digoxin packs may sit side by side on a shelf and are packaged in what could be considered similar colours. The colours of the packaging for each strength have now been altered to ensure that, while retaining readability, each of the strengths can be differentiated more easily (Figure 2).

However, George Barrie, international packaging design manager, Alpharma, comments: "Although Alpharma believes that colour helps to differentiate between packs and the company is trying to use high contrast

colours to ensure maximum readability, a US Food and Drug Administration request for comments is currently under way to explore whether the use of colour to differentiate packs is the best way forward". Alpharma says it is monitoring responses to this.

Alpharma has also started introducing Braille labelling on its product packaging, in line with the EU directive article 56a. The directive states that all medicinal products approved after 30 October this year, except for those solely intended for administration by health care professionals, eg, vaccines, are required to have the name and product strength in Braille on the secondary packaging (the carton).

User-testing of patient information leaflets (PILs) is another item on the company's agenda. Mr Barrie states: "By 2008, the MHRA will expect all PILs for branded products, generics, parallel imports and herbal products to have been user tested, unless the marketing authorisation holder can provide justification for exemption." Alpharma has a user testing forum which it currently consults on this issue, responding to group findings as appropriate.

— Packaging and labelling

Mayne Pharma, a supplier of oncology products, began redesigning its packaging and labelling three years ago. To date, about 70 per cent of the company's products have the new design.

Dawn Ashley, external communications manager for the company, explains that the company recognised the industry-wide issue regarding pharmaceutical packaging and set up an internal task force to review this concern.

The previous Mayne Pharma packaging design relied heavily on corporate livery — a blue triangle on the right hand side of the packaging — which was standard across all products. This led to concern that confusion may arise when selecting and administering products that are often densely stored in a dispensary.



Figure 3: new style packaging from Mayne Pharma

Following market research and customer feedback a new design has been introduced in the form of a coloured disc, which is used to differentiate between the company's products. An example of Mayne's new packaging and labelling design can be seen in Figure 3. Each individual product has been allocated a product colour to fill the lower half of the disc and a strength colour to fill the upper half. Additionally, the disc has been incorporated on the inside flap of the box to aid differentiation further.

Other changes to packaging and labelling include:

- The text and size have been increased to conform with the EU guideline on readability (critical information appears in as large a font as possible)
- The generic name is the predominant feature, followed by the strength and the route of administration
- The full name of the drug now appears on three non-opposing surfaces of cartons
- The product code and number of vials in the box has been removed from the front face
- All the drug information is on one side of the carton only
- Full volume strength is used rather than the mg/ml format
- The warning text is now coloured red

— Conclusion

Despite general agreement that there is no substitute for reading the label, the industry is working towards updating its labelling and packaging in line with recommendations. Pharmaceutical companies need to ensure that they are aware of any changes in practice involving their products and how these changes can impact on patient care.

According to Mr Karr: "Over the past five years, significant attention has been given to improving packaging and labelling in order to reduce medication errors. Nevertheless, the facts indicate that despite all efforts from a number of pharmaceutical companies to improve labelling and packaging, best practice is not universally applied and the problem continues to exist. Health care professionals believe that more improvements can be achieved."

— References

1. Building a safer NHS for patients — improving medication safety. London: Department of Health;2004.
2. Report to the Committee on Safety of Medicines from the working group on labelling and packaging of medicines (MLX 275). London: Medicines and Healthcare products Regulatory Agency;2001.
3. Best practice guidance on the labelling and packaging of medicines. London: Medicines and Healthcare products Regulatory Agency;2003.