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Drug packaging quality: neglected by regulatory agencies

La *Revue Prescrire*'s editorial team assesses the packaging of every drug included in its New Products column, using a strictly standardised approach.

A review of the team's work in 2004, illustrated by many examples, is available on our website at www.prescrire.org. This article presents a brief summary of trends noted in the past year in France.

Very few well-designed blister packs.

In 2004, there was a further increase in the number of products sold in bulk bottles, which carry a risk of overdose and lack the advantages of individual unit-dose blister packs (a). In addition, many of the new blister packs that appeared in 2004 were badly designed. Indeed, about 90% of blister packs for new oral medicines that we examined in 2004 did not allow each unit dose to be identified once it had been removed from the package. Only two of the 239 new blister packs were both individualised (or nearly-individualised) and entirely safe.

Many blister packs bore diagonal "wall-paper" printing that did not precisely designate each unit dose. A more serious problem is that the printing on some blister packs spanned two unit doses, creating a risk of confusion and dosing errors.

The printing on many blister packs was virtually illegible, either because the film was too reflective or because the print was too small, too pale or too dense.

The fact that some manufacturers produce excellent individual unit-dose blister packs proves that, with a little effort, it can be done.

Unsuitable dosing dispensers. The advantage of multidose oral solutions is the ability to tailor the dose to the individual patient. However, this advantage is lost if the dosing dispensers are imprecise and/or difficult to use.

Most dosing dispensers are unreliable. Some products containing potentially dangerous substances are sold with simple dispensing spoons. Some devices do not bear the product identifier, i.e. the international non proprietary name (INN) and/or the trade name. The dose is sometimes expressed differently on the dosing dispenser than on the box or patient leaflet.

In 2004 we found that only two dosing dispensers for basic oral drugs were especially well designed (see 2004 Packaging Awards, *Prescrire* Int 76). Yet, once again,

their existence proves that "where there's a will, there's a way".

Topical drugs: vague dose descriptions. In 2004 only one of the topical medications assessed in the New Products column was sold in unit-dose packaging. The remainder were all sold in multidose containers with no dosing dispensers nor clear graduations. Some examples of the imprecise vocabulary used in the patient leaflets (our translations from the French) include: "a small amount" "a walnut", a "hazelnut" or a "thin layer". Not all drugs sold for topical use are risk-free, and more precise directions for use would be welcome.

Patient leaflets: no more "copy and paste" please! We noted no global improvement in the quality of patient information leaflets in 2004.

Many leaflets are too small, resulting in tiny, bunched-up printing. Yet other leaflets are large and clearly legible, proving that companies can, with a little effort, provide patients with the information they need. It seems that too many manufacturers simply ignore the needs of the patient.

The "copying and pasting" of legally required information often leads to absurd errors. And the numerous typos show that no one really bothers to check patient leaflets.

Coherent and informative patient leaflets are the exception, not the rule, and are probably produced in response to pressure from patient groups (antiretroviral drug users, for example).

Copies: not necessarily better or worse than the originator products. The *Prescrire* editorial team noted just as many problems with copies as with originator preparations in 2004. These included: bulk bottles being used for potentially dangerous substances; confusing dosing dispensers; similar colours for different dosages; "one-size-fits-all" boxes on the outer packaging to indicate the dosing schedule (morning, midday and evening), when the actual dose regimen may consist of a single daily dose; and trade names in large print while the INN is shown in tiny characters.

Yet some conscientious generic manufacturers have demonstrated that it is possible to design and produce high-quality packaging.



Drug regulatory agencies must react!

Enactment of European Directive 2004/27/EC, which calls for improvements in secondary packaging and for pre-marketing assessment of information leaflets by patient panels, offers an opportunity for drug regulatory agencies to get their act together.

Electronic submission of marketing applications is one simple reason why drug packaging is not properly scrutinised before approval. Photographs of the different packaging items (box, labelling, leaflet) can reveal certain defects, but it is only by handling the actual packaging and by testing the dosing dispensers that one can judge whether or not they are suitable for the patients for whom the product is intended.

Drug regulatory agencies must stop listening only to drug companies' complaints. They need to get their feet back firmly on the ground and to put themselves for once in patients' and caregivers' shoes.

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a- A blister (a moulded plastic tray covered by a protective film) is said to be "individual" when each alveoli containing a unit dose bears the international non proprietary name (INN), the trade name, the dose, the lot number, and the expiry date. All these data are needed for identification and traceability purposes, regardless of how the drug is used.

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