The Prescrire Packaging Working Group

Since the very first issue of our French edition *la revue Prescrire*, we have examined the packaging of several thousand pharmaceutical products. The methodology used to analyse drug packaging was developed with the following objectives in mind:

– to alert subscribers to defective packaging that might affect a drug's risk-benefit balance;

– to familiarise subscribers with the pitfalls associated with poorly designed packaging, so that they can minimize risks, and warn regulatory authorities and patients;

– to familiarise subscribers with differences in packaging design among competing products, thus helping them choose between products that contain either the same substance or related substances with similar risk-benefit balances;

– to inform subscribers when a drug has well-designed packaging, and is therefore a preferred option.

Standardised analysis. The packaging of each product presented in the New Products section is first examined by the principal editor of the first draft of the relevant article, and then by the section chief, using a standardised questionnaire. This includes a series of questions corresponding to the different situations in which a particular type of packaging may be used, and different potential users. This assessment takes into account the drug's therapeutic value as compared to existing alternatives.

Every component of packaging is scrutinised. This includes the labelling, devices for preparing and administering the product, lids and other systems for closing containers, and patient information leaflets. The editor then rates the quality of the packaging, taking into account the therapeutic value of the drug. Important information concerning packaging, especially any inherent risks or defects, is mentioned in the published article.

The Packaging Working Group. A team specialising in the analysis of drug packaging (the *Prescrire* Packaging Working Group) is responsible for summarising and completing the editorial team's analysis. In 2006, 656 products were examined for packaging quality, and about 250 observations, positive or negative, were made and classified on the basis of four features:

– labelling quality, focusing on legibility of the international non proprietary name (INN), the dose strength, the route of administration, and the appropriateness of graphics and colours;

– the degree to which the information provided in the patient leaflet and labelling (including pictograms and other instructions for use) conveys an understanding of the role and value of the medicine in the treatment of a specific health condition or specific symptoms;

– preparation and administration of the drug, focusing on any devices provided, in the drug package or discussed in the dosing schedules mentioned in the summary of product characteristics (SPC), the treatment modalities mentioned in the leaflet, and items provided to ensure user safety;

– prevention of poisoning, through the use of a childproof closure on multiple-dose bottles containing dangerous substances, or a safety film for blister packs.

All these reports form the basis for the yearly packaging review, and for comparative analyses of packaging quality published during the year. At the end of year, the best and worst examples are re-examined in depth by the editorial team, and the laureates of the annual Packaging Awards are chosen.

Glossary. The editorial team is also responsible for developing a list of words and expressions applying to pharmaceutical packaging, as well as concepts used in a variety of documents: regulatory agency guidelines, pharmacopoeias, European and French regulatory laws, proprietary drug dictionaries, and various other documents. This research has led to the creation of a glossary of packaging-related terms and expressions, both in French and in English.

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Improving drug packaging: regulators can do better

Our 2006 packaging review identified many pharmaceutical products with poor-quality, potentially dangerous packaging.

In 2006, too many patients were exposed to a risk of severe adverse effects simply because of poorly designed packaging. Yet, all drug packaging is approved by a regulatory agency before being released onto the market. With some exceptions, drug companies design and manufacture the packaging of their products within a relatively loose regulatory framework and with little interference from regulators.

Much room for improvement. If regulators really want to make patients' well-being their first priority, they need to improve drug packaging through regulatory measures or by issuing guidelines. This should be done with the following aims:

– to ensure that the international non-proprietary name (INN) and the dose strength are clearly visible on the box and primary packaging (blister packs, bottles, vials, pens, etc.), along with the expiry date;

– to encourage the use of colours to distinguish between different dose strengths;

– to provide individual identifiers for multiple-dose blisters (pre-cutting is welcome in this case);

– to promote the use of clearly identified, appropriate and precise delivery devices, with graduations corresponding to quantities of the drug that are consistent with dosing schedules;

– to protect users from the risks of infection and toxicity (safety caps on bottles, tamperproof film on blister packs, safety devices for needles, etc.);

– to ensure that patient leaflets are informative, coherent, and legible, through pre-marketing testing by panels of potential users.

Progress and some encouraging projects. Work undertaken by the French regulatory agency on the labelling of drugs for parenteral administration is worthy of note (1). Documents posted on the Agency's website in 2006 show that thorough discussions took place on the importance of drug labelling (1).

The French agency should further assert its authority by advising manufacturers to emphasise important information such as the INN and dose strength, rather than the brand name. The Agency should no longer accept compromises that lead to the adoption of the lowest common denominator. Patients would benefit if the Agency's work were to be rapidly extended to include all types of labelling on small primary packaging items such as ampoules, vials, blister packs, and single-dose eye drops.

Directive 2004/27/EC. European Directive 2004/27/EC includes several concrete and patient-oriented improvements such as more informative labelling, the use of Braille, and obligatory pre-market testing of drug information leaflets by panels of potential users (2). ►►

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