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 premarketing 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).