2016 Prescrire Packaging Awards

The Packaging Awards focus on the quality of the packaging of drugs evaluated in 2016 in our French edition.

No Packaging Award for 2016

Prescrire's systematic reviews include evaluation of a drug's packaging. Does the packaging make the drug easy and safe to use? Do any aspects of the packaging constitute a therapeutic advance? Conversely, are any aspects of the packaging dangerous?

When analysing a drug's packaging, we consider the context in which the drug will be obtained, prepared and administered: the situations in which it will be used; the patients likely to receive it, especially children, pregnant women and elderly patients; whether it will be used in an emergency, hospital or community setting, obtained on prescription, on the advice of a community pharmacist, or bought on the patient's own initiative from a pharmacy or an internet retailer; whether or not a nurse will prepare and administer it; etc.

Every aspect of the packaging is examined to determine its quality and safety (clarity, accuracy, suitability to the situation). We examine: the information on the labelling that is useful for patient care, including the legibility of international nonproprietary names (INNs), whether different dose strengths are easily distinguishable, and any information presented graphically, such as dosing schedules and pictograms; any dosing devices supplied to prepare and administer the required doses; the measures taken to protect children from poisoning; and the quality and clarity of the information provided in the patient leaflet on dose preparation, adverse effects, and the situations and patient groups in which the drug poses a risk.

The *Prescrire* Packaging Awards are based on independent evaluations conducted by *Prescrire*'s Editorial Staff and our Packaging Working Group, free from any influence from packaging manufacturers.

YELLOW CARDS

Brintellix° 5 mg, 10 mg, 15 mg and 20 mg tablets **(*vortioxetine*)** Lundbeck (*Rev Prescrire* n° 391)
The labelling of the blister packs is ambiguous: the packs are divided into pairs of tablets by perforations, and the international nonproprietary name (INN) and dose strength are printed just once across each pair of blister pockets. Patients could mistakenly understand that in order to take the dose printed across the two blister pockets, they must swallow the contents of both pockets (2 tablets), whereas in fact the labelling refers to the dose contained in each tablet.

Spagulax° granules in multidose bags **(*ispaghula*)** Almirall (*Rev Prescrire* n° 397)
The primary packaging is a multidose bag containing 700 grams of granules. The transparent plastic bag is labelled with brief information, omitting the international nonproprietary name (INN). This multidose bag will be opened several times and is difficult to close properly after use. And its resemblance to bags commonly used for food trivialises the drug's use. It is better to choose the version supplied in single-dose sachets.

L-Thyroxine Serb° 150 microg/ml oral solution **(*levothyroxine*)** SERB (*Rev Prescrire* n° 389) • **Contramal°** Grünenthal and **Topalgic°** Sanofi Aventis, 100 mg/ml oral solutions **(*tramadol*)** (*Rev Prescrire* n° 397)
The dosing device supplied with the bottles of these drugs for dose preparation is a dropper, a device known to cause dosing errors, especially when a large number of drops must be counted. These solutions are highly concentrated, increasing the risk of an overdose or underdose if the drops are miscounted. Given that the adverse effects of *tramadol* are dose-dependent and *levothyroxine* has a narrow therapeutic index, it is particularly important to count the number of drops of these drugs accurately.

Tarka LP° 240 mg/2 mg tablets, 240 mg/4 mg tablets **(*verapamil + trandolapril*)** Mylan Medical (*Rev Prescrire* n° 389)
The two dose strengths resemble each other so closely that one could be confused for the other, resulting in an overdose or underdose of *trandolapril.*

No Award for 2016 but serious deficiencies. None of the packaging examined in 2016 met all the safety and quality standards required to earn a *Prescrire* Packaging Award. The persistent failure of pharmaceutical regulators and companies to take packaging quality seriously was yet again in evidence: umbrella brands continue to expand despite the risk of patients confusing products that have very different compositions; dangerous drugs continue to be marketed in bottles without a child-proof cap; drugs that require accurate dose preparation are supplied with inaccurate dosing devices; patient leaflets are not adequately clear about risks; etc.

Together with the annual drug packaging review (to be published in a coming issue), the *Prescrire* Packaging Awards reflect the actual situation regarding the measures being taken for the safe use of medicines. The low standards to which regulators hold pharmaceutical companies with regard to this important aspect of the quality of healthcare are disturbing, because they jeopardise patients' safety.

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RED CARDS

DANGEROUS DEFICIENCIES IN THE LABELLING OR PATIENT LEAFLET, INCLUDING UMBRELLA BRANDS

Toplexil° syrup and sugar-free oral solution **(*oxomemazine*)** Sanofi Aventis (*Rev Prescrire* n° 387)
The brand name Toplexil° printed in large, bold characters on the box overshadows the international nonproprietary name (INN). It is liable to confusion with the herbal preparation Toplexil Phyto°, as its box is also printed with the name Toplexil° in the same typographic style. Patients who mistake the *oxomemazine*-containing drug Toplexil° for the plant extract-containing preparation Toplexil Phyto° would be exposed to the sedative and antimuscarinic adverse effects of this phenothiazine antihistamine.

Fervex Rhume Jour et Nuit° tablets **(*paracetamol + vitamin C + pseudoephedrine + chlorphenamine*)** and **Fervex État Grippal°** granules in sachets **(*paracetamol + vitamin C + pheniramine*)** UPSA (*Rev Prescrire* n° 389)
These two products are liable to confusion due to the close visual resemblance between their boxes: both are printed in the same combination of colours and display the umbrella brand name Fervex° in extremely large, bold characters. Furthermore, the INNs are difficult to read on the boxes and overshadowed by the brand name. The fact that a variety of herbal preparations are also sold under the Fervex° brand only adds to the confusion.

Lysopaïne Maux de Gorge Ambroxol° lozenges **(*ambroxol*)** and **Lysopaïne Maux de Gorge Cétylpyridinium Lysozyme°** compressed lozenges **(*cetylpyridinium + lysozyme*)** Boehringer Ingelheim (*Rev Prescrire* n° 397)
These products are liable to confusion due the resemblance between their boxes: both display the umbrella brand name Lysopaïne° in large, bold characters, but also the indication, "*Maux de Gorge*" (meaning sore throat). Undue promotion is given to the various flavours of the lozenges rather than to important information such as the INNs of the drugs they contain.
This labelling makes it difficult for patients to tell that these similar-looking products have different compositions, and that some Lysopaïne° products contain *ambroxol*, which can cause allergies.

Ibupradoll° 200 mg and 400 mg tablets and soft capsules **(*ibuprofen*)** Sanofi Aventis (*Rev Prescrire* n° 398)
The patient leaflets contain insufficient information about the harms of nonsteroidal anti-inflammatory drugs (NSAIDs) during pregnancy. They fail to warn patients about concerns that NSAIDs may increase the risk of spontaneous abortion and provoke malformations when taken during the first trimester of pregnancy, or about the sometimes irreversible renal damage or pulmonary arterial hypertension reported in children following exposure to an NSAID during the second trimester. These leaflets only state that the product is contraindicated from the sixth or seventh month of pregnancy. NSAIDs should be avoided throughout pregnancy until evidence is obtained that they are safe to use before the sixth month of pregnancy.

PACKAGING THAT POSES A RISK OF POISONING FOR CHILDREN

Eucalyptine Le Brun° syrup **(*codeine + cineole*)** Hepatoum • **Néo-Codion Enfants°** syrup **(*codeine + sodium benzoate*)** Bouchara-Recordati • **Tussipax°** oral solution **(*codeine + ethylmorphine*)** Bailleul (*Rev Prescrire* n° 391)
None of the bottles used for these 3 products has a child-proof cap. Children who ingest the contents unnoticed by family members and carers would be exposed to the serious adverse effects of *codeine*, including respiratory depression. These products also have a significant amount of ethanol.

Ascabiol° cutaneous emulsion **(*benzyl benzoate*)** Zambon (*Rev Prescrire* n° 392)
The bottle lacks a child-proof cap, yet the contents could provoke seizures in children who ingest the contents unnoticed by family members and carers. It has also a significant amount of ethanol.