2014 Prescrire Packaging Awards

The Packaging Awards focus on the quality of the packaging of drugs evaluated in 2014 in the New Products section of our French edition.

2014 Packaging Award

• **Mirvaso° gel** Galderma International **(*brimonidine*)** (*Rev Prescrire* n° 373)

The child-proof cap on the tube is difficult to unscrew, thus preventing accidental ingestion by children, which can have serious adverse effects.

Prescrire's systematic analyses in the New Products section include evaluation of the drugs' packaging: is it clear from the labelling which active substance or substances the product contains? How are doses prepared and administered? Does the information in the patient leaflet help users prepare doses correctly or are errors likely?

Many factors are taken into account when analysing the quality of a drug's packaging and how convenient it is to use: the situations in which the drug will be administered; the patients concerned, in particular vulnerable populations such as children, pregnant women and elderly patients; and the setting in which it will be used (hospital or community) and supplied (on prescription only, over the counter at a pharmacy, or off the shelf).

Every aspect of the packaging articles, their quality, safety and dangers, are examined: the information on the labelling that is useful for patient care, especially the legibility of international nonproprietary names (INNs) and the dose strength; information presented graphically, such as dosing schedules and pictograms; any devices provided for drug preparation or administration; the quality and clarity of the patient leaflet, in particular information about how to prepare the doses to be administered, adverse effects, the situations and patient groups in which the drug is dangerous or must be avoided; and the measures taken to protect children from accidental ingestion.

The Packaging Awards are granted at the end of each year based on a review of the year's systematic analyses by *Prescrire*'s Packaging Working Group, in total independence, free from any influence from pharmaceutical companies or packaging manufacturers. The rules governing the Packaging Awards are available online, at english.prescrire.org.

Red cards

Dangerous shortcomings in the information on the labelling or patient leaflet

• **HumexLib état grippal°** powder for oral solution in sachets **(*paracetamol + pheniramine + vitamin C*)** Urgo (*Rev Prescrire* n° 368)
The manufacturer has chosen to print "Humex°" in bold on the box, in much larger characters than the nonproprietary names of the active ingredients, making it harder to see that it contains *paracetamol*. "Humex°" is displayed in this way on the boxes of the 20 or so products in this umbrella brand, each containing very different drugs.

• **Surbronc toux sèche dextrométhorphane sans sucre°** oral solution in sachets **(*dextromethorphan*)** Boehringer Ingelheim (*Rev Prescrire* n° 374)
The INN is insufficiently visible on the box of this new umbrella brand, which also features an illustration of someone downing a drink in one, captioned "*lemon punch flavour*": a message that trivialises the dangers of an opioid that is sometimes misused as a recreational drug.

• **AdvilMed°** 100 mg and 400 mg tablets, 5% gel, oral suspension **(*ibuprofen*)** Pfizer Santé Familiale (*Rev Prescrire* n° 369) **(a)** • **Antarène Codéine°** 200 mg/30 mg and 400 mg/60 mg tablets **(*ibuprofen + codeine*)** Élerté (*Rev Prescrire* n° 372) • **Cartrex°** tablets **(*aceclofenac*)** Almirall (*Rev Prescrire* n° 374) • **FlectorEffigel°** 1% cutaneous gel **(*diclofenac*)** Genévrier (*Rev Prescrire* n° 371) • **Ibufetum°** 5% cutaneous gel **(*ibuprofen*)** Menarini (*Rev Prescrire* n° 366) • **NurofenCaps°** 400 mg soft capsules **(*ibuprofen*)** Reckitt Benckiser Healthcare (*Rev Prescrire* n° 369) • **VoltarenActigo Intense°** 2% cutaneous gel and **Voltaren-Spé°** 1% cutaneous gel **(*diclofenac*)** Novartis Santé Familiale (*Rev Prescrire* n° 364 and n° 374)
These 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 provoke spontaneous abortion and malformations when taken during the first trimester of pregnancy, or about the sometimes irreversible renal damage reported in children following exposure to an NSAID during the second trimester. These leaflets only state that the product concerned is contraindicated from the sixth month of pregnancy. It would be better to avoid NSAIDs throughout pregnancy until this six-month cut-off has been shown to be relevant.

Packaging that poses a risk for children

• **Biocadextro enfants sans sucre°** syrup **(*dextromethorphan*)** Zambon (*Rev Prescrire* n° 373) • **Clarix toux sèche codéthyline sans sucre°** oral solution **(*ethylmorphine*)** Cooper (*Rev Prescrire* n° 365) **(a)** • **Fluimucil toux sèche dextrométhorphane adultes sans sucre°** syrup **(*dextromethorphan*)** Zambon (*Rev Prescrire* n° 374) **(a)** • **Kaneuron°** oral drop solution **(*phenobarbital*)** SERB (*Rev Prescrire* n° 372) • **Potassium Richard 3 pour cent°** syrup **(*potassium*)** Richard (*Rev Prescrire* n° 369) **(b)** • **Primpéran°** oral solution **(*metoclopramide*)** Sanofi Aventis (*Rev Prescrire* n° 373) • **Rivotril°** oral drop solution **(*clonazepam*)** Roche (*Rev Prescrire* n° 373) • **Tanakan°** oral solution **(*Ginkgo biloba*)** Ipsen Pharma (*Rev Prescrire* n° 365 and n° 368) • **Toplexil°** syrup and **Toplexil sans sucre°** oral solution **(*oxomemazine*)** Sanofi Aventis (*Rev Prescrire* n° 365)
None of the bottles of these 10 products has a child-proof cap. They therefore expose children to the risk of massive ingestion and potentially serious adverse effects.

a- This product belongs to an umbrella brand.
b- No dosing device is supplied in the box. Users are therefore forced to measure doses using a household spoon, a cause of dosing errors.

A few advances in 2014, but dire packaging persists. This year, for the first time, a child-proof cap was seen on a tube of cutaneous gel, namely *brimonidine* gel, authorised in the EU for the treatment of rosacea. This cap was difficult to unscrew in our tests and is a useful means of protecting children from accidental ingestion, which was reported during the development of this drug, provoking serious adverse effects (respiratory disorders, arrhythmia, psychomotor hyperactivity).

In contrast to this advance, numerous examples of dangerous packaging were again identified in 2014, with about 30 pharmaceuticals receiving a Red or Yellow Card.

This year's Packaging Awards once again highlight the dangers of umbrella brands in the pharmaceutical field, in which similar-looking boxes obscure the fact that the products contain very different drugs.

Yellow cards

• **Azyter**° eye drops **(*azithromycin*)** Théa (*Rev Prescrire* n° 369) • **Monoprost**° eye drops **(*latanoprost*)** Théa (*Rev Prescrire* n° 366) • **Naabak**° eye drops **(*N-acetyl-aspartyl-glutamic acid*)** Théa (*Rev Prescrire* n° 371) • **Tanakan**° tablets **(*Ginkgo biloba*)** Ipsen Pharma (*Rev Prescrire* n° 365)
The primary packaging (single-dose containers or blister packs) of these four products fails to mention the nonproprietary name.

• **Orofluco**° capsule **(*fluconazole*)** Majorelle (*Rev Prescrire* n° 373)
The international nonproprietary name is not printed on the front of the box.

• **Diffu K**° capsules **(*potassium chloride*)** UCB Pharma (*Rev Prescrire* n° 369)
The strength is expressed differently on the various packaging articles, e.g. 313 mg of *potassium* on the box and 600 mg of microencapsulated *potassium chloride* on the blister packs, which could cause dosing errors.

• **Selincro**° **(*nalmefene*)** Lundbeck (*Rev Prescrire* n° 374)
The labelling of the blister packs is ambiguous: the packs are divided into pairs of tablets by perforations, and the international nonproprietary name and dose strength are printed just once across each pair of blister pockets. Patients could understand this to mean that the contents of two blister pockets correspond to one dose, leading them to ingest a double dose.

• **Salbumol**° 0.5 mg/1 ml solution for injection and **Salbumol fort**° 5 mg/5 ml solution for IV infusion **(*salbutamol*)** GlaxoSmithKline (*Rev Prescrire* n° 366)
The graphics on the two boxes are similar and they could be confused, resulting in dosing errors.

2014 Prescrire Information Awards

The Information Awards focus on the information provided to *Prescrire* by the pharmaceutical companies whose products we examined in the New Products section of our French edition in 2014.

Honours List
(in alphabetical order)

• Oustanding:

CTRS (Cell Therapies Research & Services), EG Labo, Lucane Pharma, Mayoly Spindler

• Followed by:

Arrow Génériques, Bioprojet Pharma, GlaxoSmithKline, Mylan, Novartis Vaccines and Diagnostics, SERB

Red cards
(in alphabetical order)

Almirall, Bayer Healthcare, Biogen Idec, Bristol-Myers Squibb, Celgene, Genzyme (Groupe Sanofi), Gilead Sciences, Janssen-Cilag, Menarini, MSD, Novartis Pharma, Pfizer, Sanofi-Aventis

Prescrire's reviews are based on a thorough literature search. Pharmaceutical companies hold a wealth of information on the drugs they market or withdraw from the market. *Prescrire* requests such data (mainly clinical data, packaging, and administrative and regulatory information) so that we can compare or add them to information obtained from other sources.

As is the case with the other *Prescrire* Awards, the Information Awards are granted in total independence, free from any industry or institutional influence. The rules governing the Information Awards are available online, at english.prescrire.org.

Some companies are transparent, others uncooperative. On the whole pharmaceutical companies provide *Prescrire* with a lot of information, some new and some that we have obtained elsewhere. Certain companies respond to our requests in a timely manner and provide us with relevant, detailed documentation, including unpublished data. These companies are placed on the Honours List. The companies rated as "Outstanding" provided us with exhaustive and detailed data, without delay and sometimes without being asked.

Other drug companies fail to respond to some or all of our requests for information, or provide only limited data. Some of them delay their response, then fail to provide usable information. Others omit the most relevant data. "Red cards" are given to highlight persistent shortcomings in the provision of information by some drug companies.

Yet transparency is a sign of a responsible company, determined to make health care safer by withholding none of the data obtained during the evaluation of their drugs, including their limitations.