



2015 Prescrire Packaging Awards

The Packaging Awards focus on the quality of the packaging of drugs evaluated in 2015 in our French edition.

No Packaging Award in 2015

Prescrire's systematic reviews 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 avoid errors and dangers?

When analysing a drug's packaging, including the patient leaflet, and how convenient it is to use, we take into account every aspect of the context in which it will be used: the clinical situation; the patients concerned, in particular children, pregnant women and elderly patients; and the setting in which it will be obtained, prepared and administered (in hospital, with the intervention of a nurse, or in the community, either prescribed by a doctor,

advised by a community pharmacist, or bought by the patient from a pharmacy or an Internet retailer).

Every aspect of the packaging is examined to determine its quality and safety (clarity, accuracy, suitability to the situation). Is the drug supplied in a multidose container or is each dose packaged individually? What measures have been taken to protect children from poisoning? We examine: the information on the labelling that is useful for patient care, including the legibility of international nonproprietary

Red cards



Dangerous shortcomings in the information provided in the labelling or patient leaflet

• **Doli État Grippal**° powder for oral solution in sachets (**paracetamol + pheniramine + vitamin C**) Sanofi Aventis (*Rev Prescrire* n° 375)
"Doli" is printed in large, bold characters on the box, as it is on the boxes of all the products of the Doli° umbrella brand. This can lead to confusion between the products, some of which contain different active ingredients, such as the dangerous vasoconstrictor *pseudoephedrine*. The INNs *paracetamol* and *pheniramine* are much less obvious than "Doli".

• **Antalcalm**° medicated plasters (**diclofenac**) Pierre Fabre Médicament (*Rev Prescrire* n° 383) • **Asproflash**° tablets (**acetylsalicylic acid**) Bayer Healthcare (Consumer Care division) (*Rev Prescrire* n° 381)
• **Opalgyné**° vaginal solution (**benzydamine**) Innotech International (*Rev Prescrire* n° 375)

The patient leaflets of these products 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 or pulmonary arterial hypertension 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 or seventh month of pregnancy. It would be better to avoid NSAIDs throughout pregnancy until their use before the sixth month of pregnancy has been proven harmless.

• **Colpotrophine**° vaginal cream and capsules (**promestriene**) Teva Santé (*Rev Prescrire* n° 383) • **Gydrelle**° vaginal cream (**estriol**) Iprad Pharma (*Rev Prescrire* n° 383) • **Physiogine**° vaginal cream and pessaries (**estriol**) H.A.C. Pharma (*Rev Prescrire* n° 383) • **Trophicrème**° vaginal cream (**estriol**) Sanofi Aventis (*Rev Prescrire* n° 383)

The patient leaflets of these products contain insufficient information about the long-term harms of vaginal oestrogens, which are identical in nature to those of oral oestrogen therapy: arterial and venous thrombosis, as well as breast and endometrial cancer.

Packaging liable to cause dangerous dose preparation errors

• **Vaccin BCG SSI**° powder and solvent for suspension for injection (**BCG**) Sanofi Pasteur MSD (*Rev Prescrire* n° 385)

The vial contains 10 to 20 doses of the vaccine and the graduation scale on the syringe supplied in the box corresponds to 10 to 20 times the recommended dose. These flaws are liable to cause overdoses and adverse effects. This product already received a *Prescrire* Red Card in 2007. Its packaging has not been improved and serious errors continue to occur.

• **Venlafaxine Abbott**° sustained-release tablets (**venlafaxine**) Mylan Medical (*Rev Prescrire* n° 379)

This antidepressant (with an unfavourable harm-benefit balance) is taken once a day, yet the dosing schedule on the box shows 3 boxes, labelled "morning", "midday" and "evening". The confusion this is likely to cause could result in overdoses and more, or more severe, adverse effects.

• **Diacomit**° hard capsules and powder for oral suspension in sachets (**stiripentol**) Biocodex (*Rev Prescrire* n° 384) • **Votubia**° dispersible tablets (**everolimus**) Novartis Pharma (*Rev Prescrire* n° 378)

Neither the pharmaceutical forms nor the packaging of these products is suitable for preparation of the recommended paediatric doses, which could lead to confusion, wrong-dose errors and adverse effects.

• **Cometriq**° 20 mg and 80 mg hard capsules (**cabozantinib**) Swedish Orphan Biovitrum (*Prescrire Int* n° 167)

The complexity of the packaging of this cancer drug is liable to cause confusion and dose preparation errors: the doses prescribed are 140 mg, 100 mg or 60 mg, while the dose strengths available are 20 mg or a mixture of 20 mg and 80 mg capsules. The labelling on the boxes does not help clarify the situation.

Packaging that poses a risk of poisoning to children

• **Atarax**° syrup (**hydroxyzine**) UCB Pharma (*Rev Prescrire* n° 385)
• **Diacomit**° hard capsules (**stiripentol**) Biocodex (*Rev Prescrire* n° 384)
• **Normison**° tablets (**temazepam**) Primius (*Rev Prescrire* n° 377) • **Simbrinza**° eye drops (**brimonidine + brinzolamide**) Alcon (*Rev Prescrire* n° 381)

None of the bottles used for these products has a child-proof cap. Children could therefore ingest their contents, with potentially serious consequences.

names (INNs) and the dose strength; information presented graphically, such as dosing schedules and pictograms; any devices provided for preparing or administering the required dose; the quality and clarity of the information provided in the patient leaflet on how to prepare the doses to be administered, on adverse effects, and on the situations and patient groups in which the drug poses a risk.

The Packaging Awards are based on the assessments conducted by *Prescrire's* Packaging Working Group, in total independence, free from any influence from packaging manufacturers.

No Award in 2015, but various dangers to report. None of the packaging examined in 2015 satisfied all the requirements concerning safety and therapeutic advance to earn a *Prescrire* Packaging Award. However, the dangers identified are illustrated in this year's edition by the 20 or so products that received a Red or Yellow



2015 Prescrire Information Awards

The Information Awards focus on the information provided to *Prescrire* by the companies whose products we examined in the New Products section of our French edition in 2015.

Honours List

(in alphabetic order)

• **Outstanding :**
EG Labo,
Lucane Pharma

• **Followed by :**
Arrow Génériques,
Codexial Dermatologie,
GlaxoSmithKline

Red cards

(in alphabetic order)

Allergan, Bayer Healthcare
(Pharmaceuticals),
Biogen Idec,
Bristol-Myers Squibb,
Crinex, Gilead Sciences,
Meda Pharma, Menarini, Pfizer

Yellow cards



• **Monosept[®]** eye drops in single-dose containers (**cethexonium bromide**) Horus Pharma (*Rev Prescrire* n° 376)

The INN is not displayed on the single-dose containers.

• **Zovirax[®]** 200 mg/5 ml oral suspension (**aciclovir**) GlaxoSmithKline (*Rev Prescrire* n° 386)

The new dosing device (a double-ended measuring spoon, one end for measuring 2.5 ml and the other 5 ml) is unsuitable and could cause wrong-dose errors, given that the recommended dose is 5 ml or 10 ml.

• **Ribavox[®]** tablets (**ribavirin**) Bioprojet Pharma (*Rev Prescrire* n° 386)

The boxes and bottles are covered with fanciful graphics (a tablet depicted as a rocket, clouds and the sun) that increase the resemblance between the three dose strengths and could lead to confusion when dispensing them or preparing doses.

Card: some lack a child-proof cap, others provide no means of preparing doses for children, some patient leaflets fail to warn users of known dangers.

A non-exhaustive list of packaging flaws. Increasing numbers of drugs are placed on the market in packaging that could lead to difficulty or poorly evaluated dangers, for example:

cancer drugs such as cytotoxic agents, in bulk bottles; insulins marketed at different concentrations; and the continued growth of umbrella brands.

The *Prescrire* Packaging Awards and the annual drug packaging review (to be published in a coming issue) reflect the true state of affairs as regards the safe use of drugs. The overall picture is disturbing.

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Pharmaceutical companies hold a wealth of information on the drugs they market or withdraw from the market. They have a responsibility to share this information, in part to help ensure that their drugs are used appropriately and to protect patients from certain risks.

As part of its systematic literature search, *Prescrire* requests clinical data, packaging, and administrative and regulatory information from drug companies, then compares them with information obtained from other sources. *Prescrire's* Information Awards reflect how each company assumes this responsibility to share information.

Still too little transparency on the part of drug companies in 2015. On the whole, pharmaceutical companies supply *Prescrire* with a lot of information, some new and some that we have obtained elsewhere. But they are less cooperative when asked to provide relevant, detailed documen-

tation containing unpublished data, which for example could include details about adverse effects.

Some companies choose to be transparent. These companies are placed on the Honours List. And those rated as "Outstanding" provided us with useful, detailed data without delay and sometimes without being asked.

Other 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. Some omit the most important data. Red Cards are given to highlight persistent shortcomings in the provision of information by certain drug companies.

In 2015, few pharmaceutical companies embraced transparency by agreeing to share with health professionals all the data they hold, in particular data on adverse effects.

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