2011 Prescrire Packaging Awards

The Packaging Awards focus on the quality of packaging for drugs evaluated during the previous year in the New Products section of our French edition (in 2011: issues 327 to 338).

Throughout the year, the editorial staff systematically examines the packaging of several hundred pharmaceutical products. This provides us with an opportunity to identify high-quality packaging and to detect dangerous packaging that is a potential source of confusion and errors, in order to inform our readers.

Painstaking analysis. Every aspect of the packaging is examined: the labelling on boxes, blister packs, vials, syringes; any devices provided for drug preparation or administration; caps and stoppers, and the legibility and quality of the information provided in the patient leaflet regarding the conditions of use, adverse reactions and interactions, and any recommended non-drug measures.

Independent rating. At the end of each year, the Packaging Awards are granted following a review of the year's standardised forms by the *Prescrire* Packaging Working Group, in total independence and with no input from drug or packaging manufacturers (rules available at english.prescrire.org).

Too many red and yellow cards in 2011. *Prescrire* has been examining drug packaging for three decades, representing more than 5000 packages analysed. This activity contributes to various projects, including the articles published in *Prescrire*, actions aimed at improving professional practice (such as the *Preventing the Preventable* programme at evitable.prescrire.org), and contributions to European public consultations.

This year's Packaging Awards highlight the poor overall quality of drug packaging in 2011.

The method used to prepare the Awards has remained unchanged over the years, meaning that the steady increase in the number of yellow and red cards simply reflects the state of the market. High-quality packaging is now so rare that the product to which the Packaging Award was granted in 2011 does nothing but to bring together all the basic requirements for quality packaging. The packaging in question was designed by *Établissement pharmaceutique* of *Assistance Publique-Hôpitaux de Paris* (AP-HP) (EPHP) (**a**), which is no doubt more sensitive to the real needs of hospital practitioners than to the greed of BigPharma shareholders.

Even after France's Mediator° (*benfluorex*) scandal, health authorities are still failing to pay sufficient attention to the quality of drug packaging.

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a- EPHP is part of Ageps (Agence générale des équipements et des produits de santé) of AP-HP, Paris's public hospitals. Ageps provides various services, including evaluation and purchase of healthcare products, clinical research and development, and the manufacture and availability of drugs with marketing authorisations.

Packaging Award

- **Mexilétine AP-HP° capsules** Ageps-EPHP (***mexiletine***)

The labelling highlights information necessary to prevent medication errors, i.e. the international nonproprietary name (INN), the dosage, and the pharmaceutical form.
The individual blister pockets of the blister packs are each labelled and precut (**a**).
The packaging promotes correct preparation of the drug in daily practice, whether in the hospital or not.

a- A unit-dose blister pack is defined by the labelling of each blister pocket with the INN, the dosage, the pharmaceutical form (or the route of administration), as well as the batch number and the expiry date.

Yellow cards

(in alphabetical order)

- **Diarfix° capsules** Cristers (***racecadotril***) (*Rev Prescrire* n° 328)
- **Grazax° oral lyophilisates** Alk Abelló (***allergenic extract of Timothy grass pollen***) (*Rev Prescrire* n° 328)
- **Hexaquine° tablets** Du Gomenol (***quinine + thiamine***) (*Rev Prescrire* n° 337) (**a**)
- **Levofree° single-dose eyedrops** Chauvin (***levocabastine***) (*Rev Prescrire* n° 328). The printing on Levofree° single-dose units is easily rubbed off.
- **Lovavulo° Gé tablets** Codépharma (***ethinylestradiol + levonorgestrel***) (*Rev Prescrire* n° 327). Lovavulo° Gé blister packs mention the INN but in tiny, poorly legible characters.

The primary packaging (blister pack or single dose units) for these products does not clearly mention the name of the active ingredient.

- **Septidose° Gé unit-dose cutaneous solution** Neitum (***chlorhexidine***) (*Rev Prescrire* n° 336)

The route of administration is not clearly mentioned on the front of the box, even though confusion over the route of administration has been reported with other single-dose units containing various products used to treat infants. The packaging includes an obscure pictogram that is supposed to indicate the age of the patients.

a- The company announced that a label including the INN but accompanied by a much bigger brand name will be added, see Rev Prescrire n° 340 p. 156.

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Red cards (by type of packaging defect, and then in alphabetical order)

Bulk bottles with potentially fatal contents:

- **Imeth° 10-mg tablets** Nordic Pharma (***methotrexate***) (*Rev Prescrire* n° 331)
- **Méthotrexate Bellon°** 2.5-mg tablets Sanofi Aventis (***methotrexate***) (*Rev Prescrire* n° 331)
- **Novatrex°** 2.5-mg tablets Pfizer (***methotrexate***) (*Rev Prescrire* n° 331)

Bulk bottles for these 3 products lack a child-proof safety cap, creating a risk of ingestion of a tablet that has accidentally fallen out of the bottle, and accidental ingestion of a lethal dose by a child (**a**).

a- *The company stated that the risk was negligible compared with that of overdose due to dosing error, see Rev Prescrire n° 340 p. 156.*

Patient leaflets that fail to provide adequate information to pregnant women and thus endanger their unborn children:

- **Adviltab rhume° tablets** Pfizer Santé Familiale (***ibuprofen* + *pseudoephedrine***) (*Rev Prescrire* n° 332)
- **Antarène Codéine° tablets** Élerté (***ibuprofen* + *codeine***) (*Rev Prescrire* n° 332)
- **Bi-Profénid° LP tablets** Sanofi Aventis (***ketoprofen***) (*Rev Prescrire* n° 327)
- **Compralfène° gel** Gifrer Barbezat (***diclofenac***) (*Rev Prescrire* n° 336)
- **Flector Tissugel Héparine° plasters** Genévrier (***diclofenac* + *heparin***) (*Rev Prescrire* n° 329)
- **Nifluril Enfants° suppositories** Bristol-Myers Squibb (***morniflumate***) (*Rev Prescrire* n° 336)
- **Profémigr° tablets** Sanofi Aventis (***ketoprofen***) (*Rev Prescrire* n° 327)
- **Tendol° gel** Népenthès (***diclofenac***) (*Rev Prescrire* n° 336)
- **Voltarène Enfant° suppositories** Novartis Pharma (***diclofenac***) (*Rev Prescrire* n° 338)

The labelling of these nine nonsteroidal anti-inflammatory drug (NSAID)-containing products states that they are only contraindicated from the sixth month of pregnancy. The labelling fails to stipulate there is an increased risk of miscarriage and malformations with exposure in the first trimester, as well as life-threatening renal and cardiovascular fetal toxicity after NSAID exposure during the second trimester.
Paediatric suppositories examined in 2011 may be mistakenly used by pregnant women who are falsely reassured by their indication for paediatric use.

Contradictory dosing schedules on the boxes:

- **Colokit° tablets** Mayoly Spindler (**sodium phosphates**) (*Rev Prescrire* n° 329)
The outer packaging includes a two-box treatment schedule with the words “date” and “hour” in the singular, whereas the 32 tablets must be ingested in eight sequences, each with 250 ml of water; this creates a source of confusion in the preparation and administration of this product, thus increasing the risk of adverse effects with this laxative (including life-threatening electrolyte disorders (**b**)).

b- *According to the company, details about dosing schedules should be given during the visit prior to colonic investigation. Also a risk management plan is underway, see Rev Prescrire n° 340 p. 156.*

Paediatric packaging unsuitable for children:

- **Picoprep° sachets of powder for oral solution** Ferring (***sodium picosulfate* + *magnesium oxide* + *citric acid***) (*Rev Prescrire* n° 330)
There is no specific paediatric dosage or packaging: the labelling states that children under 9 years old should receive one-half or one-quarter of a sachet, creating a risk of dosing errors and adverse effects of laxatives (including life-threatening electrolyte disorders) (**c**).
- **Cozaar° preparation for oral suspension** Merck Sharp & Dohme (***losartan***) (*Rev Prescrire* n° 329)

Multiple sources of error during preparation of this product for hypertensive children, due to:
– The excess volume (273 ml) of solvent, and the excess capacity (40 ml) of the bottle provided for the reconstituted suspension;
– The need to “shake before use” is not mentioned on the bottle, but only on the patient leaflet; this can result in a solution that is not sufficiently homogeneous.
– The oral syringe is graduated in millilitres, representing a potential source of error when converting the prescribed dose (in mg) to the required volume (in ml).

c- *The company announced that dosing spoon will be available in 2012, see Rev Prescrire n° 340 p. 156.*

Adult medicines too readily accessible to children:

- **Humex toux sèche oxomémazine° syrup** and **oral solution** Urgo (***oxomemazine***) (*Rev Prescrire* n° 337)
No child-proof safety cap is provided; the label represents what looks like a cream dessert, a starry night and a moon; and the graduated cups carry a risk of overdose.
The multiple flaws of this self-medication product, part of an umbrella brand, create a risk of preventable overdose and misuse (for insomnia), especially in children.
- **Bipreterax° tablets** Servier (***perindopril arginine* 10 mg + *indapamide* 2.5 mg**) (*Rev Prescrire* n° 327)
- **Buccosoin° mouthwash solution** Merck Médication Familiale (***chlorhexidine* + *chlorobutanol*, 42.8% ethanol**) (*Rev Prescrire* n° 335)
- **Célestamine° tablets** Merck Sharp & Dohme (***betamethasone* + *dexchlorpheniramine***) (*Rev Prescrire* n° 331)
- **Dolko° oral solution** Therabel Lucien (***paracetamol***) (*Rev Prescrire* n° 334)
- **Eludrilpro° mouthwash solution** Pierre Fabre Médicament (***chlorhexidine* + *chlorobutanol*, 42.8% *ethanol***) (*Rev Prescrire* n° 338)
- **Euphonyll toux sèche dextrométhorphane° syrup** Mayoly Spindler (***dextromethorphan***) (*Rev Prescrire* n° 330) (**d**)
- **Flucalyptol toux sèche pholcodine° syrup** Zambon (***pholcodine***) (*Rev Prescrire* n° 327)
- **Primalan° syrup** Pierre Fabre Médicament (***mequitazine***) (*Rev Prescrire* n° 337)
- **Primpéran nourrissons et enfants°** and **Primpéran enfants° paediatric oral solutions** Sanofi Aventis (***metoclopramide***) (*Rev Prescrire* n° 328)

There is no child-proof safety cap on the bottles of these 10 products, creating a risk of overdose in children. Overdose exposes them to the adverse effects of the drugs concerned or their excipients (high *ethanol* concentration), including cardiovascular, hepatic and neurological disorders, depending on the substance ingested.

d- *According to the company, a "feasibility study" for a safety cap will be conducted, see Rev Prescrire n° 340 p. 156.*

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