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Drug packaging in 2008: not enough progress



● **Among the packaging systems that Prescrire analysed in 2008, very few met all of our quality criteria. Unsuitable packaging, which could put patients at risk, is often the result of choices made by manufacturers.**

● **The risk of error is higher in certain products intended for self-medication, children, partially sighted patients, pregnant women, use in hospitals and other institutions.**

● **There are even some rather disturbing trends: labelling of blister packs that sacrifices the legibility of the international nonproprietary names (INNs) for the sake of multilingualism, excerpts from the package leaflet printed on the back of the box.**

● **We found improvements in many packaging items again this year: this should motivate health professionals concerned about high-quality care to choose the better ones and to push for more progress.**

Rev Prescrire **2009; 29 (304): 144-145.**

In 2007, the *Prescrire* packaging workshop noted an overall improvement in the packaging for drugs marketed in France (1).

What was the verdict for 2008?

Not enough progress. The packaging that Prescrire analysed in 2008 satisfies regulatory requirements. However, packaging design sometimes does not adequately take into account quality of care and patient safety. Packaging very rarely met all of our quality criteria (see the 2008 Packaging Awards in April 2009 issue). Yet again, drug packaging in 2008 reflects the fact that manufacturers are making the same old choices:

– labelling that emphasises commercial details (the invented name, company graphics and logos) instead of information that is useful for patient care. The international nonproprietary name (INN) is often less prominently displayed, particularly on blister packs (*montelukast*-Singulair° *la revue Prescrire* 295; *pseudoephedrine-cetirizine*-Humex Rhinite Allergique° *la revue Prescrire* 295; *rizatriptan*-Maxalt° *la revue Prescrire* 300). Occasionally the INN is not even printed on the blister pack (*ketotifen*-Zaditen° capsules *la revue Prescrire* 297; *ambroxol*-Lysopadol° *Prescrire International* 100). The INN is not printed on the external surface of some transdermal patches, which means they cannot be identified once they are applied to the skin (*testosterone*-Testopatch° *la revue Prescrire* 293; *nicotine*-Niquitin° *la revue Prescrire* 301);

– ambiguous labelling of the concentration for injectable drugs (*oxycodone*-Oxynorm° *la revue Prescrire* 291; *temsirolimus*-Torisel° *la revue Prescrire* 297);

– problems with devices used for dose preparation: no dosing device provided (*dextromethorphan*-Vicks toux sèche miel° *la revue Prescrire* 299; *mecasermin*-Increlex°, this issue p.111); inappropriate dosing devices, such as those graduated in ml rather than in mg for the active ingredient (*fosamprenavir*-Telzir° oral suspension *la revue Prescrire* 295; *hydroxyzine*-Atarax° syrup *la revue Prescrire* 291); complex dosing devices, such as the *fentanyl*-Ionsys° iontophoretic transdermal device, which was withdrawn from the market shortly after its introduction (this issue page 110);

– absence of a safety cap on bottles containing dangerous substances: for example, an easy-to-open cap for a product containing sufficient doses of quinine to be fatal for a child (*quinine-crataegus* (dry hawthorn extract)-Okimus° *la revue Prescrire* 297);

– package leaflets that lack details (*levothyroxine L*-Thyroxine Serb° *la revue Prescrire* 299) or that are overly complex (*urokinase*-Actosolv°, this issue p.118).

These drawbacks can lead to confusion between drugs, errors during dose preparation or even accidental poisoning (1).

Packaging unsuitable for at-risk patients. Sometimes packaging is inappropriate for particular patient populations, certain types of therapy or the method of supply:

– unsuitable for children (dangerous illustration on the package leaflet showing the administration of *fentanyl*-Durogesic° *la revue Prescrire* 292; inappropriate dose strength for *succimer*-Succicaptal° *la revue Prescrire* 292);

– unsuitable for blind or partially sighted patients (*la revue Prescrire* 304);

– unsuitable for therapy that requires the use of single-dose units, particularly in hospitals or other institutions (*la revue Prescrire* 296; *la revue Prescrire* 297);

– unsuitable for self-medication (*la revue Prescrire* 295; *cetirizine*-Actifed Allergie Cétirizine° *la revue Prescrire* 296: illegible INN on blister packs; *pholcodine*-Valda toux sèche sans sucre° and *paracetamol-pseudoephedrine-vitamin C*-Valda Rhume° *la revue Prescrire* 302: trivialisation of the risks by the use of herbal medicine labelling);

– unsuitable for women of child-bearing age (ambiguous information in package leaflets about the risks of non-steroidal antiinflammatory drugs (NSAIDs) during the first trimester of pregnancy (*ibuprofen*-Advilcaps° and Adviltab° *Prescrire International* n° 100)) (2).

New concerns. A worsening trend in 2008: several cases in which the labelling spans more than one unit dose and is particularly difficult to read. Particulars are printed in several language and in small, thick lettering, sacrificing the legibility of the INN in favour of multilingualism, for marginal savings in manufacturing costs (18 languages with *sitagliptin*-Januvia° *la revue Prescrire* 295 and *sitagliptin*-Xelevia° *la revue Prescrire* 299; 13 languages for *duloxetine*-Cymbalta° *la revue Prescrire* 300).

Another striking observation: dangerous statements or illustrations were found in some package leaflets. In addition to the examples mentioned above for some self-medication products and the *fentanyl*-Durogesic° patch, a misleadingly reassuring statement minimises the adverse effects of *nilotinib*-Tasigna°: *"most of the side effects are mild to moderate and will*

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generally disappear after a few days to a few weeks of treatment" (3).

Another trend was confirmed: blister packs in which the labelling that specifies the daily dose spans a group of 2 to 4 unit doses (*ivabradine*-Procoralan° *la revue Prescrire* 292). This type of labelling could lead to a 2- to 4-fold overdose.

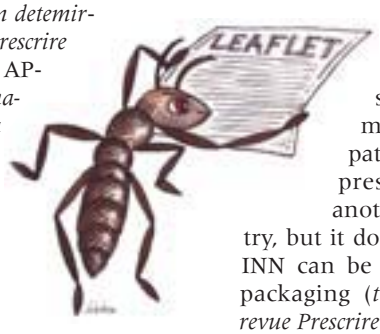
Another practice that could lead to confusion: excerpts from the package leaflet that are printed on the back of the box for certain prescription drugs (*risedronic acid-calcium-colecalciferol*-Actonel Combi° *la revue Prescrire* 293; *ethinylestradiol-drospirenone*-Jasminelle continu° *la revue Prescrire* 300). Spreading drug information around on different parts of the packaging creates a risk that the package leaflet will not be read in its entirety. Some of these boxes come in the form of a "wallet" (3 folding flaps which act as both box and blister pack), for example Jasminelle° and Jasminellecontinu°. As the package leaflet cannot be placed inside the wallet for these two products, cellophane wrap holds the leaflet and the wallet together. Once the cellophane has been removed, there is a high risk that the package leaflet will be lost (**a**).

Some positive trends nevertheless. Fortunately, some manufacturers have made good choices, such as packaging systems that have been correctly designed from the beginning (*insulin detemir*-Levemir° Innolet° *la revue Prescrire* 294; *methadone*-Méthadone AP-HP° capsules *Prescrire International* 99; *exenatide*-Byetta° *la revue Prescrire* 295). There are some very rare examples where all of our packaging quality criteria have been met (*methadone*-Méthadone AP-HP° and *miltefosine*-Miltex°, see *Prescrire International* 100).

A few packaging systems which initially had a rather unsatisfactory administration device have been improved (*meningococcal C vaccine*-Meningitec° *la revue Prescrire* 295; *rotavirus vaccine*-Rotarix° *la revue Prescrire* 296; *epoetin alfa*-Eprex° *la revue Prescrire* 302; *risperidone*-Risperdalconsta° LP *la revue Prescrire* 302). There were also examples where ambiguous labelling of drug concentrations has been clarified (*levetiracetam* for injection-Keppra° *la revue Prescrire* 304; *lopinavir-ritonavir*-Kaletra° *la revue Prescrire* 291).

Some packaging for drugs that were initially restricted to hospital use and later became available in retail pharmacies were adapted appropriately (*ornidazole*-Tibéral° *la revue Prescrire* 297: single-dose blister packs; *idarubicin*-Zavedos° *la revue Prescrire* 291: single-dose bottles with child-proof caps; *miltefosine*-Miltex° *la revue Prescrire* 300 and *Prescrire International* 100 p 82).

The progress that was noted in 2007 for the patient information leaflets of drugs licensed through the European centralised procedure has been maintained, probably due to their evaluation by patients. Several package leaflets provide more detailed information to patients and caregivers concerning drug disposal (*papillomavirus types 16,18 vaccine*-Cervarix° *la revue Prescrire* 292). Other package leaflets mention brand names currently used in other European member states. This may help minimise confusion for patients who buy their prescription drugs in another European country, but it does not mean that the INN can be left off the primary packaging (*timolol*-Geltim LP° *la revue Prescrire* 292).



Access to Braille has expanded and many package leaflets refer to the French association Handicapzéro, which supplies package leaflets and labels in Braille. This improvement should become more widespread in 2009.

In practice: keep up the pressure. In the 28 years that *Prescrire* has been evaluating drug packaging, one has to admit that examples of high-quality packaging have been rare.

Healthcare professionals and patients therefore need to continue to remain vigilant and to maintain the pressure so that manufacturers improve the quality of their packaging for drugs and devices. Health authorities also need to demand higher standards.

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a- *During the marketing authorisation procedure for Jasminelle°, Hungary refused to approve its packaging because the risk of the wallet becoming separated from the package leaflet constituted "a serious public health concern". Following arbitration, the European Committee for Medicinal Products for Human Use (CHMP) did not recommend modifying the packaging (ref 4).*

Selected references from Prescrire's literature search.

1- Prescrire Editorial Staff "Drug packaging in 2007: some improvements, still many risks" *Prescrire* 2008; **17** (94): 82.

2- Prescrire Rédaction "AINS en début de grossesse et risque de fausse couche" *Rev Prescrire* 2007; **27** (281) : 192-193.

3- Commission européenne "Notice-Tasigna (nilotinib)" 19 November 2007: 8 pages.

4- CHMP "Avis suite à saisine formée sur le fondement de l'article 5, paragraphe 11 - Yasminelle et dénominations associées" 17 June 2008: 1 page.



See the new Prescrire in English website for an additional text from *Prescrire International*:

Counterfeit drugs: recognising the real issues

- Despite the lack of reliable data on the true extent of drug counterfeiting, media reports are becoming increasingly frequent and alarming.
- Confusion is sometimes deliberately maintained between counterfeit drugs and defective products, legal drug copies (including generics) and parallel imports.
- The priorities, particularly in poor countries, are to enforce stricter regulation of the legal drug supply system and to guarantee all patients access to high-quality drugs at reasonable prices.

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