

OTC drug sales authorised in France

● **The French authorities have decided to authorise over-the-counter sales of some drugs in community pharmacies, beginning in mid-2008. The drugs must be displayed in a section of the pharmacy dedicated to these products. This measure will likely concern more than 200 products already used for self-medication, some of which are more harmful than beneficial.**

In recent months the French authorities have been preparing to authorise over-the-counter (OTC) sales of certain drugs in community pharmacies (1-4). Thus, at a time when some countries are considering to restrict OTC sales of certain drugs for public health reasons, the French authorities are moving in the opposite direction (5). What does this decision mean in practice?

Not compulsory for pharmacists. In early April 2008, it appeared that pharmacists would not be obliged to make drugs available over the counter in their stores (3,6).

OTC drugs will have to be "displayed in a separate and clearly identified space (...), close to the counter used for drug dispensing, so that monitoring by the pharmacist is ensured" (4,6).

They must not be mixed with other "non-drug" products available in pharmacies, such as cosmetics and dietary supplements (3,4).

A list of eligible drugs. Drugs available over the counter are placed on a "positive list" established by the French Health Products Safety Agency (Afssaps) (4). An initial list distributed by the press suggests that most of the drugs on this list are already available without a prescription and are already intended for advice from a pharmacist, or they have already been advertised directly to the public (6).

There is nothing very new on this first list of about 200 products (3,4,6), most of which are intended for pain relief, ear, nose and throat disorders, respiratory disorders, digestive disorders, and smoking cessation (6).

The list includes some drugs with negative risk-benefit balances, such as flurbiprofen (a nonsteroidal antiinflammatory drug) for sore throat (6-8).

Packaging must be monitored. The packaging of OTC drugs ought to "be adapted to the dose regimen and duration of treatment". In addition, "the contents of the patient leaflet (...) should provide appropriate information for patients" (3,4).

In addition, the outer packaging (box) must be equipped with a tamperproof seal to ensure that it has not already been opened (6). However, experience suggests that companies consider OTC drug boxes more as a means of advertising their products, with similar brand names and impressive, often misleading graphics (9).

In practice. OTC drug sales are authorised in France, but will not be compulsory: it will be left to individual pharmacists to decide what they feel is in their customers' best interests (10). This means pharmacists can decide which drugs to sell over the counter and to provide specific advice concerning the drugs their customers choose. They will also have to ensure that over-the-counter drugs are not overused and do not become just an ordinary consumer product.

©Prescrire

Editor's note

These measures have been in effect since July 2008.

Selected references from Prescrire's literature search.

1- Prescrire Rédaction "Automédication: un projet au service des firmes, mais pas des patients" *Rev Prescrire* 2007; 27 (283): 340-341.

2- Prescrire Rédaction "Médicaments d'automédication en accès libre: projet suspendu" *Rev Prescrire* 2007; 27 (284): 422.

3- AFP "Des médicaments en libre service dans les pharmacies en mai, selon le ministère" 11 March 2008: 2 pages.

4- "PMF devant le comptoir au premier semestre 2008" *Les Nouvelles Pharmaceutiques* 2008; (353): 8.

5- Prescrire Editorial Staff "Self-medication: will the move from prescription-only to over-the-counter will benefit the public?" *Prescrire Int* 2008; 17 (95): 124.

6- Auguste O and Gadhoum F "Certains médicaments bientôt en libre-service" + "La liste complète des molécules concernées" 11 March 2008. www.lefigaro.fr accessed 20 March 2008: 6 pages.

7- Prescrire Rédaction "16-1-2. Patients sous vasoconstricteur décongestionnant" *Rev Prescrire* 2007; 27 (290 Drug Interactions supplement).

8- Prescrire Rédaction "Strefen®: soins ou gavage?" *Rev Prescrire* 2007; 27 (281): III de couv.

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

10- Prescrire Rédaction "L'éthique toujours présente au cœur de nos métiers" *Rev Prescrire* 2007; 27 (290): 948.

