PRESS RELEASE

The Ansm recommendations for drug labeling:
a move towards neutral packaging for medication ?

AFIPA DENOUNCES THE MEASURE AS COUNTER-PRODUCTIVE AND DANGEROUS FOR PATIENTS

Paris, May 31, 2018 - Afipa (the French Pharmaceutical Industry's Association for Responsible Self-medication) responds to the Ansm recommendation - published on February 28 - to standardize the packaging of certain medications. The Association cautions against this measure, which will lead to confusion for patients and is not supported by any objective data, in particular regarding self-medication drugs[1]. It warns that the accidents which may be caused by this new recommendation - as demonstrated in a study carried out in April 2018 - will come under the sole responsibility of the authorities which endorsed it.

A counter-productive measure, which increases the risk of confusion instead of reducing it

This recommendation will have a very strong impact on the packaging of self-medication drugs: it will make the brand name less visible by enhancing instead the names of the active ingredients. The implementation tests carried out by several pharmaceutical companies clearly demonstrate **decreased legibility** and the resulting **similarity between packs**. It is also worth noting that some units will require larger packs, in order to add statements not stipulated in the Public Health Code for self-medication drugs and to meet minimal size requirements for certain items. Therefore, this modification will adversely affect both the environment (more cardboard, more transportation with larger packs ...) and the organization of pharmacies (pharmaceutical robots ...).

[1] Self-medication signifies that people can treat conditions on their own using approved over-the-counter drugs, which are safe and effective if used within the specified guidelines (WHO 2000 definition) under the guidance of a pharmacist.

Afipa wishes to draw the attention of Ansm and the Ministry of Health to the **risk of confusion between different drug packs resulting from this new measure.** Not only it will not contribute to Ansm's stated goal of reducing medication errors, but it will be harmful to patients' health. Afipa is all the more concerned because Ansm has not documented the risk of error linked to the current labeling of self-medication drugs, which is what motivated the new recommendation.

An approach based on biased figures, with no scientific backing

Afipa points to the lack of tangible evidence to support the recommendation or evaluate its impact, since Ansm has not justified its approach by communicating any figures or analysis of medication errors directly related to self-medication. In fact, Ansm claims that 30% of medication errors can be attributed to packaging, without specifying what percentage of these mistakes occurred in the hospital or elsewhere, without even clarifying the circumstances or the context of these incident reports.

According to Ansm's pharmacovigilance report of October 2016, out of the 186 types of mistakes identified since 2005, only 5 have involved confusing 2 different oral self-medication drugs. Since we know that self-medication drugs represent one in seven drugs sold in pharmacies, this extremely low error rate proves how illogical and unjustified this measure is. Implementing this recommendation, on the other hand, may well increase the risk of confusion for the patient.

New packs produce 25% of errors

A study conducted in April 2018 by the Opinionway Research Institute, on a representative population sample of over 1,000 people, provided evidence of the danger to patients caused by the packaging recommendation. This study showed that about **a quarter of the population**[2] **is less able to correctly identify the indication of drugs in Ansm-recommended packaging** compared to current packaging. The new packaging was considered not so easy to read (34% vs 52%), not so easy to understand (32% vs 50%), not so easy to find in the pharmacy (22% vs 41%) or in the family medicine cabinet (24% vs 45%), and not so clearly displaying the indication (36% vs 54%).

Finally, **up to 96% of respondents did not know the name of the active ingredient or exactly what it was used for.** That is why, rather than minimizing the brand name, Afipa had proposed to Ansm to make the names of the active ingredients more legible – this information being necessary for proper use of the drug.

A similar study which surveyed pharmacists showed that this measure did not benefit them either, since current packaging had a 98% rate of correct identification. Nevertheless, most pharmacists are concerned for patient safety after the new recommendation becomes effective.

Even if patients receive advice and support from the pharmacist when choosing their treatment, once at home they must be able to identify the medication appropriately on their own.

The brand name: a fundamental benchmark for the self-medication sector

In this context, the brand name constitutes a valuable link between the patient and the drug. Self-medication is practiced by the patient, with the advice of the pharmacist, but without a doctor's prescription giving the name of the active ingredients. Consequently, **the brand name helps patients identify and memorize which drug** they are taking and this brings additional **security for self-medication**, whereas the names of the active substances often prove complex.

[2] Results are 99% significative

Weakening the brand name's visibility breaks this link and puts the patient at risk.

Contrary to what is being done elsewhere in Europe, Ansm, a public health agency, is thus creating an additional confusion factor for the patient, in a sector where the risk is already under control.

Patient safety remains Afipa's priority. This recommendation, with all its potentially dramatic consequences, must be withdrawn. Afipa is requesting this withdrawal, and calls for a reworking of the project with the authorities, in a cooperative and constructive manner.

At the end of April the Association filed an action for annulment with the Council of State.

The recommendation published by Ansm suggests printing on certain drug packs the names of the active ingredients in a font larger than what's used for all other information, including the brand name or laboratory name. The text also recommends concealing certain distinctive markings (such as the brand logo) and repeating the information.

This recommendation is directed to applicants and holders of marketing authorizations. It deals with how to label packaging for medications in solid oral form (excluding homeopathy).

Afipa is a public health partner and professional association, which represents manufacturers who produce and market health products available over-the-counter in pharmacies (self-medication drugs, medical devices and food supplements).

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