Drug packaging in Europe: what factors drive progress?

A number of measures and guidelines have been introduced in Europe and France to improve the safety of drug packaging.

**Progress arising from European guidelines.** The implementation of a new European pharmaceutical directive in late 2006 improved the regulatory framework and guidelines in the EU, making medicines safer (1,2). Their impact late 2005 improved the regulatory framework and guidance of a new European pharmaceutical directive in the EU, making medicines safer (1,2). The EMA published a guideline for the prevention of medication errors, such as the INN, poor-quality dosing devices, and patient leaflets that lack important information present in the documentation intended for health professionals or with limited information about excipients. What’s more, umbrella brands include drugs bearing the same easy-to-remember brand name but containing different active ingredients (7-10).

The ANSM has made some progress since 2015, issuing some much-needed recommendations that will greatly increase patient safety if put into practice: withdrawing umbrella brands, giving due prominence to INNs, and encouraging the use of unit-dose blisters and accurate dosing devices (6-9).

**Progress driven by civil society.** The progress made in Europe in the 2000s owes much to the work of the Medicines in Europe Forum, composed of organisations representing patients, consumers, mutual health insurance providers, and health professionals, including Prescrire (1). This progress is also due to the regular participation of various organisations in public consultations on drug packaging organised by drug regulatory agencies. The International Medication Safety Network (IMSN) and Prescrire contributed in this way to the ANSM recommendations in favour of the prohibition of umbrella brands in France in 2018 (1,6-16).

Campaigning of a French support group (Apecas) for the parents of children with birth defects caused by valproic acid played a major role in the introduction of a warning pictogram on boxes of drugs known to be dangerous during pregnancy in France in 2017 (17).

The patient leaflet for the HIV testing device Autotest VIH® shows the exceptional quality that can be achieved when patient organisations are involved, while the packaging of a similar device (Insti®), designed without the collaboration of patients, has many shortcomings (18,19).

**Remain proactive.** Healthcare professionals and patients also have a very important role to play by reporting packaging flaws that caused or could potentially cause medication errors. In 2017, several French hospital-based healthcare professionals reported the potential for error associated with the coexistence of dosing devices marked with different graduation scales for Haldol® oral solution (haloperidol).

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6-Prescrire Rédaction “Projet de l’ANSM de recommandations sur les étiquetages des formes orales solides: un premier pas encourageant vers plus de sécurisation de l’usage des médicaments, à optimiser” 12 November 2017: 8 pages.
7-Prescrire Editorial Staff “The proposed recommendations on drug brand names by France’s Health Products Agency: a plan that maintains dangerous name confusion” 14 December 2016: 4 pages. english.prescrire.org.
12-International Medication Safety Network “IMSN encourages regulators and companies to improve medication safety at the global level” Press release, 21 November 2016: 2 pages.