

Paris, 14 December 2016

The ANSM's proposed national recommendations on drug brand names: a plan that maintains dangerous name confusion

The *Prescrire* team is keen to participate in the public consultation launched by the French National Agency for Medicines and Health Products Safety (ANSM) concerning its proposed recommendations on drug brand names (1).

Prescrire has been involved for a long time in the prevention of medication errors and adverse effects caused by confusion between drug brand names (2-4). These errors can occur when health professionals prescribe drugs (by hand or electronically), dispense drugs (while reading the prescription, selecting from a menu, storing or selecting products from a shelf) and administer drugs (selecting products from ward stock). They can also occur when patients or their carers buy drugs from a pharmacy or an internet retailer, and administer them at home.

We welcome the ANSM's decision to release its draft recommendations on brand names for public consultation. The ANSM also mentioned that recommendations on drug labelling are currently being developed. Having systematically analysed the packaging of thousands of medicinal products, *Prescrire* is aware of the urgent need for higher drug packaging and labelling standards. We encourage the ANSM to rapidly launch a public consultation on its draft recommendations on labelling. In the meantime, we have incorporated this issue into our comments on the ANSM's proposed recommendations on brand names

Inconsistencies between guiding principles and agencies' practices. Article 168-1 of the Treaty on the Functioning of the European Union stipulates: "*a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*". The ANSM's first strategic priority in its 2015-2018 Objectives and Performance Contract is "*to guarantee a high level of safety for all health products throughout their life cycle*".

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The public consultation organised by the ANSM provides an opportunity to point out that the European Medicines Agency (EMA) guideline on brand names does not give sufficient consideration to patients' interests or to human factors at each stage of brand name development, at both industry and administrative level. *Prescrire* and the International Medication Safety Network (IMSN) have developed constructive proposals to shift the focus of European policy in this area towards patient safety. We propose in particular that the EMA and all national drug regulatory agencies should:

- publish a list of brand names that have led to name confusion;
- facilitate the reporting of drug name errors by health professionals and patients;
- adopt and publish a method for assessing the risk of confusion before marketing authorisation;
- stop accepting umbrella brands;
- adopt stricter standards for the naming of fixed-dose combinations;
- revert to more prudent use of abbreviations and suffixes, as these lead to confusion;
- involve patients in the search for improvements (4,5).

International nonproprietary names (INNs) are constructed using informative common stems. As a result, errors caused by confusion between INNs are less frequently reported than brand name confusion errors, for example in the ANSM's list of pairs of confused drug names. It is therefore important to display INNs prominently on drug packaging, especially since, quite rightly, drugs are identified solely by their INN in the drug interactions section of patient leaflets.

Overcrowded brand names. The name of a medicinal product has a commercial purpose and is defined thus in Article 1(20) of Directive 2001/83/EC: "*Name of the medicinal product: The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder*". The spirit of the Directive does not support the principle of brand names consisting of more than one term, and neither do the European templates or guidelines. Furthermore, most brand names approved through the centralised procedure are single-term names, apart from rare exceptions such as those that include the brand name of an inhaler device.

However, increasing numbers of drugs approved through certain decentralised European procedures and, especially, many drugs approved through national procedures, under the sole responsibility of the ANSM (and the Afssaps before it), have long brand names consisting of a hotchpotch of terms or belong to umbrella brands liable to cause confusion (6).

The ANSM's proposals on brand names reflect how difficult it is for a Member State to replace deeply entrenched national practices that cause drug confusion with the EU concept of a "name of the medicinal product". For example, France's drug regulatory agencies have long fuelled confusion between the notion of a product's brand name (that ought to be a single-term name, apart from a few rare exceptions) and the administrative notion of its "full name", which is used in marketing authorisation documents, stated in the SPC and printed on the labelling.

The full name consists of its invented name together with other terms such as the INN, dose strength and route of administration. The use of the full name in drug databases has caused medication errors through confusion at various stages of the medication use process, particularly in computerised systems. Another issue lies with the particulars listed in Annex IIIa of the marketing authorisation (labelling) that are useful to patients, for example the target population or the flavour of an oral drug. In national marketing authorisations and frequently in European decentralised or mutual recognition procedures, some of these particulars are being incorporated into the drug's name rather than being simply displayed on the packaging. Drug names sometimes also include a term referring to a symptom or disease ("common cold", "allergy", etc.). This practice has undoubtedly been adopted to reduce confusion between products belonging to the same umbrella brand, but it would clearly be more effective to put a stop to umbrella brands altogether. Umbrella brands, in which up to 20 products with different compositions are marketed under the same brand name, cause wrong-drug errors, wrong-population errors and overdoses, and constitute an increasing threat to patient safety (6).

Prioritise patient safety. The ANSM would fulfil its remit to protect human health and guarantee the safety of health products, in accordance with the spirit of the Treaty on the Functioning of the European Union and the Directive, by evaluating brand names before authorisation focusing on preventing confusion and harm, by limiting brand names to a single term (apart from rare exceptions), by relegating other particulars (that are only useful to patients) to the labelling, and by demanding that INNs are the most prominently displayed information on drug packaging. This would effectively put a stop to the umbrella brands that are currently proliferating on the French market. The urgent need to banish umbrella brands was recently affirmed at a meeting in October 2016 between IMSN and major drug regulatory agencies, including the EMA (7).

Instead however, the ANSM's proposed recommendations on brand names are muddled, contradictory and ambivalent (1). For example, although single-term invented names are recommended on line 193, this important safety measure is undermined by a variety of waivers that will maintain the current dangerous French practice of brand names consisting of a hotchpotch of terms, and that above all will endorse the concept of umbrella brands.

Put a stop to umbrella brands. In summary, *Prescrire* urges the ANSM to revise its draft recommendations on brand names in accordance with the spirit of the Treaty on the Functioning of the European Union, with Directive 2001/83/EC and with the ANSM's own remit, in a way that maximises patient safety, abandoning national practices that cause medication errors by creating confusion. We also ask the ANSM to stop legitimising the continued presence of umbrella brands on the market, given the dangers they pose for patients, by challenging their regulatory compliance.

For more information:

- 1- ANSM "Recommandations à l'usage des demandeurs et titulaires d'autorisations de mise sur le marché et d'enregistrements relatives aux noms des médicaments" September 2016: 8 pages.
- 2- Prescrire Rédaction "Confusion entre noms commerciaux: entretenue par les agences du médicament" *Rev Prescrire* 2007; **27** (290): 941-945. Translated in: Prescrire editorial Staff "Drug regulatory agencies maintain confusion between brand names" *Prescrire International* 2008 ; **17** (94) : 83-86.
- 3- Prescrire Rédaction "Confusion entre noms commerciaux (suite)" *Rev Prescrire* 2009; **29** (307): 380-382.
- 4- Prescrire Rédaction "Noms commerciaux: la sécurité des patients doit primer sur la promotion des marques" *Rev Prescrire* 2014; **34** (368): 462. *Prescrire's* full response is freely available at <http://www.prescrire.org/Fr/1/194/48278/2920/2508/SubReportDetails.aspx> (French) and <http://english.prescrire.org/en/79/207/46302/2919/2506/SubReportDetails.aspx> (English)
- 5- International Medication Safety Network "IMSN – Position statement. Making medicines naming, labeling and packaging safer" October 2013; 13 pages (http://english.prescrire.org/Docu/Images/IMSN/IMSN_MakingMedicinesNamingLabelingAndPackagingSafer2013.pdf)
- 6- Prescrire Rédaction "Gammes ombrelles: une réévaluation sur le fond s'impose à l'ANSM" *Rev Prescrire* 2015; **35** (376): 139.
- 7- International Medication Safety Network "IMSN encourages regulators and companies to improve medication safety at the global level" Press release, 21 November 2016: 2 pages.