

# Confusion between commercial names: EMA more concerned with defending trademarks than patient safety

Prescrire's response to the EMA consultation on drug brand names (August 2013)

## Summary

● *Prescrire* has examined the proposed revision of the European Medicines Agency (EMA) guideline on the acceptability of brand names for drugs processed through the centralised procedure (revision 6) released for public consultation in June 2013.

● Since the EMA adopted the previous version of the guideline in 2007, the North American drug regulatory agencies have improved their methodology for detecting the risk of confusion between brand names. The EMA has not: this revision provides very little progress in terms of preventing the risk of confusion between drugs.

● This revision will primarily help pharmaceutical companies to protect trademarks and manage their brand: no effort has been made to encourage a naming system that clearly states the drug's international nonproprietary name (INN-based naming); trademarks can be expanded indefinitely by adding qualifiers, which will notably encourage the development of "umbrella" ranges; previously authorised names can be recycled; greater differentiation is required between "biosimilars"; etc.

● Instead of working to protect the integrity of the INN system and its common stems, the EMA proposes ending systematic consultation with the WHO INN Programme. Yet collaboration between these organisations should actually be strengthened, notably to tackle the issues of "biosimilars" and modified INNs.

● *Prescrire's* response to this proposed EMA revision includes ten concrete proposals that would shift the focus of the guideline onto preventing confusion between brand names.

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The growing awareness of the risk of errors and adverse effects caused by confusion between brand names owes much to independent medication error-reporting programmes, such as the Institutes for Safe Medication Practices (ISMP), that alert health professionals, patients and health authorities by reporting the most significant cases (1). The lists of potentially confusing drug names pairs, compiled by these programmes and others, reveal that the risk of confusion is much higher when drugs are referred to by their brand names rather than their international nonproprietary names (INNs) (a)(1).

When a company applies for marketing authorisation (MA) for a drug throughout the European Union, i.e. through the centralised procedure, the European Medicines Agency (EMA) must examine its brand name. This involves the committee for medicinal products for human use (CHMP) submitting the names proposed by the pharmaceutical company to a specialised working party, called the Name Review Group (NRG).

In June 2013, the EMA released for public consultation a proposed revision of its guideline on the acceptability of brand names for drugs processed through the centralised procedure (2,3). It is the 6<sup>th</sup> revision of this guideline: the previous revision, which was adopted in 2007, did not place sufficient emphasis on patient safety (b). Since the adoption of the previous revision, the North American drug regulatory agencies have improved their methodology for assessing proposed drug names, in order to better prevent the risks associated with confusing one drug brand name with another. Has the proposed revision of the EMA guideline taken advantage of these advances to improve patient safety?

## The North American drug regulatory agencies have raised their standards

Although it was long considered impossible to predict confusion between drug names, the development of psycholinguistic methods and human factors engineering has led the North American drug regulatory agencies to reconsider their methodology for assessing the acceptability of proposed drug names and to impose stricter requirements on industry.

**The FDA: a pioneering approach to assessing brand names.** Two reports by the Institute of Medicine (IOM), published in 2000 then in 2006, prompted the US Food and Drug Administration (FDA) to become involved in preventing medication errors caused by confusion between drugs (c)(4,5,6). The FDA now conducts a "pro- ▶▶

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*a- In the US, where drug labelling procedures differ from those in Europe, the United States Pharmacopeia examined 26 604 reported medication errors caused by confusion between drug names, collected by the MedMarx programme and by the ISMP between 2003 and 2006. Brand names were implicated more often than nonproprietary names: 839 (57%) of the 1470 drug names reported to have been involved in name look-alike and/or sound-alike medication errors were brand names (ref 22). Brand names accounted for almost all of the name confusions reported since 2005 to the French drug regulatory agency (152, i.e. 93.8%, including 6 food supplements and 1 medical device), while INNs were responsible for about 10 (ref 23).*

*b- Prescrire responded to the public consultation on the previous version of this guideline (refs 1,24). However, the EMA refused to shift the focus of its proposed revision onto patient safety, and did not incorporate the proposals put forward by Prescrire or the International Medical Safety Network (IMSN), aimed at preventing medication errors resulting from confusion between brand names (refs 24-26).*

*c- The first report, entitled "To err is human", advised the US Food and Drug Administration (FDA) to "require pharmaceutical companies to test proposed drug names to identify and remedy potential sound-alike and look-alike confusion with existing drug names" (ref 4). The second report, entitled "Preventing medication errors", urged the FDA to "better incorporate the principles of cognitive and human factors engineering to address remaining issues concerning information presentation and nomenclature" and more particularly to use failure mode and effects analysis (FMEA) (ref 5).*

► proprietary name review” to assess the safety of brand names, based on a submission that includes the corresponding labelling and packaging (including any measuring and administration devices), to which the company is free to add its own assessments of the name, labelling and packaging (d)(6,7).

The FDA proprietary name review takes into account the context in which the drug will be used and includes: searching databases for similar names and analysing the degree of similarity; listing reported cases of medication errors caused by confusion; simulation studies of the various phases of medication use; and actively searching for potential sources of confusion using failure mode and effects analysis (FMEA) (6,7).

The proprietary name review forms part of the marketing authorisation dossier, which is made available to the public on the FDA website (in the Drugs@FDA section).

**The Canadian drug regulatory agency is planning an even more thorough system.** Canada’s drug regulatory agency, Health Canada, has been examining drug names since 2006, in accordance with a guideline that aims to reduce the risk of medication errors caused by similarity between brand names (8). When pharmaceutical companies submit their proposed brand name, they must also submit an assessment of the potential for drug name confusion, including: a search for similar drug names; orthographic and phonetic computer analysis; prescription testing studies; a review of published cases of medication errors involving the same name or a systematic assessment of the proposed name (8).

Due to “significant variation in the amount, type and quality of the evidence submitted by sponsors”, this guideline is now being revised in order to obtain “objective information in a standardised format” from pharmaceutical companies (9). In the proposed revision, Health Canada will only examine one brand name at a time, once the company has completed a three-step process: a search for drugs with similar names and for published error reports; simulation testing, including

screen-based simulations of auditory and visual perception; and a report summarising the findings of the searches and simulations and an FMEA. The proposed revision sets out the methodology to be used in detail, with examples, including lists of attributes to take into consideration to determine the degree of similarity between drug names (9).

**In summary**, as of mid-2013, the North America drug regulatory agencies have recognised that suitable methodology exists for analysing the risk of confusion between brand names. The assessments conducted by these drug regulatory agencies open the way to preparing and examining a medication error risk assessment dossier on drugs before their market introduction (10).

### **The EMA’s evaluation: minimal improvement to searches for similarity between brand names**

Following a meeting on its role in the prevention of medication errors, one of the priority actions announced by the EMA was to revise its guideline on drug names review in order to “minimise name confusions” (proposed action 4.3) (11).

Yet just like previous versions, this guideline merely describes the administrative process adopted by the Name Review Group (NRG) for dealing with the brand names proposed by pharmaceutical companies. Despite proposing several improvements to the process for searching for similarity between brand names, the latest revision does not specify the methodology to be used for detecting and evaluating similarity, and it therefore falls far short of the methodological standards of the North American drug regulatory agencies.

**Methodology for identifying similarity with existing brand names must be specified.** The proposed revision introduces several new requirements: consideration must be given to the phonetics and pronounceability of brand names in the various European languages (3§4.1.4, 1.161-162), and proposed

brand names that are too alike will be rejected, for example if they differ by just one letter (3§4.1.9).

The EMA proposes that the NRG will search for similarity between the proposed brand names and existing brand names (products that have been authorised, suspended, withdrawn/revoked or for which an MA application has been submitted in any Member State) (3§4.1.1, 1141-144). However, the NRG limits its search to the previous 5 years, with an even shorter period for drugs that were not marketed in the European Union, and only extends the search period if the MA was withdrawn due to serious safety concerns (3§4.1.1, 1141-152). It is hard to see the point of reducing the effectiveness of the review by imposing these limits on the search period.

The proposed revision does not state which database the NRG will use for this search. Does it really have access to a database containing every drug available in the European Union, whether they were approved through a centralised, decentralised, mutual recognition or national procedure, and in which it could determine the brand names under which they were marketed in every country of the European Union?

This search ought to include every drug marketed in every Member State (e). For example, *Prescrire’s* analyses identified similarity between the following pairs of brand names: Bemedrex° (Easyhaler° *beclometasone*, authorised through the mutual recognition procedure) and Bermex-ex° (*exemestane*, authorised through the decentralised procedure); and Fendrix° (hepatitis B vaccine, authorised through the centralised procedure) and Fentrix° (*fentanyl* trans-

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d- A pilot programme was supposed to evaluate the pharmaceutical industry’s ability to produce its own drug names assessments, but the final date for submissions had to be postponed due to insufficient industry response (refs 7,27).

e- The joint website of the European national drug regulatory agencies (HMA: Heads of Medicines Agencies), which provides information about decentralised and mutual recognition procedures, makes no mention of the recommendations for preventing confusion between brand names in these types of MA procedures.

dermal patch, authorised through the decentralised procedure). If these products were marketed in the same Member State, such easily confused brand names would expose European patients to the risk of medication errors.

**No systematic evaluation of brand names on packaging.** The risk of confusion between brand names also depends on the way in which they are displayed on packaging and labelling (f)(6). It is important to ensure that the INN is as visible as the brand name on packaging, in accordance with current European guidelines, because the INN is a crucial differentiation safeguard against drug confusion errors (12).

However, although the EMA should check these aspects systematically, the guideline restricts the submission of packaging and labelling mock-ups or specimens by pharmaceutical companies to cases in which abbreviations or suffixes are used, and only if concerns or risks have been identified (3§4.1.5,1.183-187,13). This ad hoc approach falls far short of the procedure requested by *Prescrire*, in which the safety and usability of the packaging and labelling of new products would be evaluated systematically, as part of the MA process and well before the MA is granted, and the findings published in a “medication errors public assessment report” (10).

**In summary**, this revision provides very little progress in terms of preventing the risk of confusion between drugs, falling far short of the EMA’s stated aims and the standards set by the North American drug regulatory agencies.

## **A guideline that still focuses on trademark protection and brand management**

A drug’s INN is quite simply its real name: it is the name of the active ingredient it contains, from which a curative or preventive effect is expected. There is no obligation to give a drug an invented name in order to market it in the European Union: a combination of the INN and the name

of the MA holder is sufficient to designate a product (g)(14). It is the solution adopted when the brand names proposed by a company are rejected (3§6.5.3).

Such INN-based names enable health professionals to be sure which drug they are prescribing or recommending. Provided that the commercial details included in the name do not overshadow and detract from the INN, INN-based names are safer for patients than invented names. First, they reduce the likelihood of medication errors caused by confusion between drugs, and secondly they help prevent adverse effects associated with drug-drug interactions, because drugs are referred to by their INN in the interactions section of patient leaflets. INN-based names also make patients more aware of the composition of the drugs they are taking and enable them to spot any that contain the same active ingredient, and therefore avoid an overdose.

**No encouragement to use INN-based names.** This revision proposes that the EMA’s drug name review procedure will be identical for all three types of name: invented names, the nonproprietary name followed by a trademark, and the nonproprietary name followed by the name of the MA holder. In addition, INN-based names will no longer be considered as “default options” (3§1.1.90-93).

The EMA should instead be encouraging the use of INN-based names composed of the INN and the name of the company (see proposal 5).

**Trademark rights come first.** Trademarks are an important means of marketing, creating customer loyalty and establishing protection from competition (15). This has led to a phenomenon in which a single drug is authorised under a variety of trade names, which may for example correspond to different indications (“multiple applications” (3§4.3.9)) or legal statuses (orphan, prescription-only or over-the-counter medicines). The use of multiple brand names for the same drug creates a high risk of confusion, while the names offer no clues as to the products’ effects.

## **Proliferation of “umbrella” branding.**

By considering that the addition of a qualifier to an existing invented name constitutes a new invented name (3§5), the EMA implicitly accepts “umbrella” branding, in which a range of drugs with different compositions have the same name (e.g. Vicks<sup>o</sup>) (h). Their labelling gives prominence to the qualifiers, sidelines the INNs, and reinforces similarity within the range by employing the same graphics.

Yet while the EMA encourages the proliferation of “umbrella” brands in this way, the revised guideline proposes no methodology aimed at preventing confusion between products belonging to the same “umbrella” brand.

## **Recycling previously used names.**

It is in pharmaceutical companies’ financial interests to reuse brand names, because users have already memorised them. Recycling can occur before a drug is marketed, for example in France: the oral contraceptive Clereal<sup>o</sup> was initially going to be a combination of *chlormadinone* and *ethinylestradiol*, but was ultimately launched as a progestin-only contraceptive, containing *desogestrel*.

But the reuse of a brand name of a drug that has already been marketed will always pose a risk of medication error to patients and health professionals who have memorised the former meaning of this name. It can also interfere with pharmacovigilance ▶▶

f- The FDA requires applicants to submit samples of the packaging and any dosing and administration devices to evaluate this risk of confusion (ref 6).

g- According to Article 1(20) of Directive 2001/83/EC, a drug’s name “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” (ref 14).

h- As of August 2013, in France, the umbrella brand Vicks<sup>o</sup> includes 9 over-the-counter drugs with very different compositions: *Pastilles médicinales Vicks menthol eucalyptus<sup>o</sup> lozenges (camphor + eucalyptus oil + levomenthol + thymol + tolu balsam + benzyl alcohol)*; *Vicks toux sèche dextrométhorphane adultes miel<sup>o</sup> lozenges (dextromethorphan)*; *Vicks 0,133 % adultes toux sèche miel<sup>o</sup> syrup (dextromethorphan)*; *Vicks sirop pectoral 0,15 %<sup>o</sup> syrup (pentoxyverine)*; *Vicks expectorant guaïfénésine 1,33 % adultes miel<sup>o</sup> syrup (guaifenesin)*; *Vicks expectorant ambroxol 0,6 %<sup>o</sup> oral solution (ambroxol)*; *Vicks expectorant ambroxol 30mg<sup>o</sup> tablet (ambroxol)*; *Vicks vaporub<sup>o</sup> ointment (camphor + turpentine oil + levomenthol + eucalyptus oil + thymol)*; and *Vicks inhaler<sup>o</sup> inhalation stick (camphor + levomenthol)*.

► signals if a delayed adverse effect, such as a cancer or endocrine disorder, emerges years after treatment with the original drug was discontinued.

Yet the NRG states that it is prepared to examine every situation, including the reuse of brand names of drugs that have already been authorised, without even excluding those withdrawn for safety reasons or that have already been marketed for different indications (i)(16).

**In summary**, this revision is a direct continuation of the previous revision that was overly concerned with defending manufacturers' trademarks. Rather than protecting patients from the risk of medication errors caused by confusion between brand names, its main focus is trademark protection and brand management, for the benefit of the pharmaceutical industry (by failing to encourage the use of INN-based names and by allowing the unrestricted expansion of "umbrella" ranges and the reuse of previously authorised names, etc.).

### EMA bypassing the WHO INN Programme

INNs are developed by the World Health Organization (WHO) following precise rules, and often incorporate common stems that enable users to recognise substances belonging to the same pharmacological and/or chemical group. The aim is to develop a unique name for every substance that is used as a drug, enabling users to identify drugs even when they are marketed under multiple brand names. The name should be recognisable and pronounceable in every country in the world and, as far as possible, not liable to confusion.

By referring to WHO resolution WHA46.19, the revision of the EMA guideline reminds European and national drug regulatory agencies of their responsibility to protect the integrity of the INN system and its common stems, and in particular to refuse to allow trademarks derived from them, to avoid any confusion between invented names and INNs (j) (3§4.2,1212-214;17).

**Worrying trend with "biosimilars"**. The revision of the EMA guideline demands greater differentiation between the brand names of "biosimilars", particularly if the originator and copies differ in form, dose strength or indications (3§4.3.5). Given the current trend among companies to attempt to obtain a different name for every copy of a drug derived from biotechnology, consultation with the WHO INN Programme is essential. Yet this revision would make consultation with the INN Programme optional, while allowing outside opinions to be sought from approved experts (3§6.2).

**More prudence required with modified INNs.** The WHO INN Programme has also developed a standardised nomenclature for salts, esters, and relatively complex radicals or chemical groups that would be inconvenient to write (and read) using normal chemical nomenclature. An invariable nonproprietary name is added to the INN of the drug concerned to produce an "international nonproprietary name (modified)", or INN<sub>M</sub>, in which the modifying term is easily recognisable.

When an INN<sub>M</sub> is used, the EMA must ensure that the substance is correctly designated in accordance with WHO rules. The situation is less clear when the modifying term is missing or has not been finalised by the INN Programme (3§4.3.6,1.267-277). The EMA recommends employing the name used by pharmacopoeias, health authorities or even pharmaceutical companies, provided it complies with the INN Programme's rules of nomenclature for radicals and chemical groups (18,19).

It would be more appropriate to refer (or have the company refer) requests for additional modifying terms to the INN Programme, which can then determine whether the new term needs to be created. It is an important issue because of the high likelihood of confusing non-equivalent drugs that cannot be distinguished by the INN of the active moiety alone, and the consequences can be fatal in some cases, e.g. injectable amphotericins (available as *amphotericin B deoxycholate*, a

phospholipid complex, or a liposomal formulation), and liposomal derivatives of *doxorubicin* or *cytarabine* (20).

### Shift the focus of the proposed revision of EMA's guideline onto strengthening patient safety

Again in 2013, as it already did in 2007, *Prescrire* urges the EMA to shift the focus of its proposed revision of its guideline on drug brand names and makes 10 concrete proposals (read in box on page 5). Priority should be given to preventing medication errors caused by confusion between drug brand names. And it is also essential that end users, i.e. health professionals and patients, can identify the drugs present in medicinal products, to determine their pharmacotherapeutic group and therefore deduce their known adverse effects.

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i- According to a position paper made public in 2011, once a brand name has been proposed and accepted by the NRG, it is available to the company for a period of 3 years, which can be extended by 3 more years at the request of the company: freely when it has not already been used or proposed in support of an MA application; with re-evaluation on a case-by-case basis when an MA has already been granted or when the drugs are to be used differently (ref 16). This position paper was not released for public consultation but was based on discussions with the pharmaceutical industry (refs 16,28).

j- This has not always been respected. Although the EMA ought to prohibit brand names derived from recognised common stems or INNs, it has tolerated drug brand names that include a common stem, particularly for drugs produced using biotechnology, for example: *Biograstim*<sup>®</sup> and *Ratiograstim*<sup>®</sup> are brand names for filgrastim drugs that were authorised in Europe and wrongfully include the common stem *grastim*; *Proleukin*<sup>®</sup> is the brand name of an aldesleukin drug that was authorised in France and wrongfully includes the common stem *leukin*, which denotes interleukin 2 (IL-2) analogues and derivatives; etc.

## Ten concrete proposals to shift the focus of EMA's proposed revision of its guideline on drug brand names

### 1- Improve the methodology used in Europe to assess the risk of confusion between commercial names before market introduction.

For pharmaceutical companies to predict the potential risk of confusion between commercial names, the EMA should explicitly recommend a reproducible methodology and publish the methodology employed by the Name Review Group (NRG) responsible for reviewing the acceptability of drug brand names, following the example of the North American drug regulatory agencies, and as recommended by the Council of Europe. These systematic assessments should include testing by health professional and patient panels under routine conditions of use.

The findings of these name assessments should be published, together with the results of assessments of the safety and usability of the packaging and labelling of new drugs, in a "medication errors public assessment report" that would form part of the MA dossier.

### 2- Broaden the search for similarity between brand names to include all the drugs marketed within the European Union.

Drug name confusion can arise with any brand name, so the rules must be broadened to include the evaluation of brand names of drugs authorised through decentralised and mutual recognition procedures.

### 3- Provide access to basic information about every drug marketed in the European Union.

Even if it is only to enable searches for potential similarity, a database must be established that includes every drug authorised in the European Union, regardless of the MA procedure used. It must include at least the following information: their INN, their brand names (which often differ between Member States unless they were authorised through the centralised procedure), their legal status and their authorised indications.

### 4- Publish the list of drug names prone to confusion.

The EMA must keep an up-to-date, publicly accessible list of names that have caused medication errors due to

confusion in any Member State of the European Union (a). When errors have led to adverse effects, the EMA must also distribute explicit alerts.

### 5- Strongly encourage the use of INN-based drug names.

Drug names consisting of the INN and the name of the MA holder should be strongly encouraged, for example by:

- respecting the principle that the INN-based name should be the "default option";
- providing a simplified, fast-tracked drug name review application to companies that opt for an INN-based name;
- waiving the variation fee when pharmaceutical companies decide to replace an invented name with an INN-based name; etc.

When this naming scheme is not used, demand and check that the INN is more visible than the invented name on labelling.

### 6- Refuse to allow the proliferation of "umbrella" branded drugs.

Through the advantages offered to pharmaceutical companies to develop "umbrella" brands, i.e. ranges of medicines with very different compositions that have the same name, the drug regulatory agencies of the European Union are exposing patients to the risk of medication errors and preventable adverse events. An in-depth EMA review of the dangers inherent in "umbrella" brands is needed in order to better evaluate the need for restriction or even prohibition, in the name of consumer protection.

### 7- Revert to more prudent use of abbreviations and suffixes.

Abbreviations and suffixes are a source of confusion, and their use must therefore be strictly limited. It is high time the NRG drafted an illustrative list of acceptable abbreviations and suffixes. The use of abbreviations and suffixes must once more be made the exception rather than the rule.

### 8- Refuse to allow the recycling of previously used brand names.

The EMA must not permit the reuse of brand names that have already been used, in order to prevent both medication errors and inter-

ference with pharmacovigilance signals in the event of the original drug causing adverse effects that emerge years after discontinuation.

### 9- Cooperate effectively with the WHO INN Programme.

In order to benefit from the advantages of the INN system and its common stems, the EMA must continue to consult the WHO INN Programme systematically, particularly to tackle the issue of "biosimilars" and modified INNs.

### 10- Involve patients and independent medication error-reporting programmes in the search for improvement.

Discussions on the risk of confusion between brand names must not be limited to drug regulatory agencies and drug companies. Independent medication error-reporting programmes as well as consumer organisations should also be consulted on this issue.

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*a- Lists of potentially confusing drug name pairs have been published in particular by: the United States Pharmacopeia (USP) (refs 22,29), the Institutes for Safe Medication Practices (ISMP) of the US (ref 30), and Spain (ref 31), the Pennsylvania Patient Safety Reporting System (PA-PSRS) (ref 32), and the French drug regulatory agency (ANSM, formerly Afsaps) (ref 23).*

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