European Medicines Agency

SUBMISSION OF COMMENTS ON
GUIDELINE ON THE ACCEPTABILITY OF NAMES FOR HUMAN MEDICINAL PRODUCTS
PROCESSED THROUGH THE CENTRALISED PROCEDURE
CPMP/328/98, Revision 5 - 5 February 2007

COMMENTS FROM PRESCRIRE <CONTACT PERSON>

GENERAL COMMENTS

Prescrire is an independent drug bulletin supporting a healthcare practitionners continuing education programme, owned by an independent organisation aimed to achieve healthcare improvement in the interests of patients first, formally called “Association Mieux Prescrire”.

The magnitude of the use of trademark names of medicinal products in European healthcare is mainly the consequence of the marketing pressure from the pharmaceutical companies, as private owners of these trademarks. Everyday medication errors are related to trademark names of medicinal products in Europe.
As a consequence, European citizens are threatened by adverse drug effects, sometimes serious, which is an inacceptable situation and a public healthcare concern.
The risks related to trademark names of medicinal products are not acceptable because they are preventable for several reasons: the use of trademark names of medicinal products is not mandatory; the international nonproprietary names (INN) should be systematically used as usual names and made proheminent at all stages of the medication use system, on the package leaflets, and both on the inner and on the outer packages of medicine products (a concern not enough taken in account in the “Draft Guideline on the readability of the label and package leaflet of medicinal products for human use”).
As the responsible public body for delivering the marketing authorisation through the centralised procedure, the European Medicines Agency is fully accountable of the safety of the trademark names of medicinal products in Europe. Therefore, as a part of the evaluation of the safety of medicinal products in the authorisation procedure, the Guideline on the acceptability of names for human medicinal products must guarantee that the health status of European citizen will not be threatened by medication errors related to trademark names.

Prescrire wellcomes several improvement to the previous guidelines (Release 4), particularly the broadening of assessing criteria adressing safety concerns in proposed trademark names (§ no.2.1.1), and encourages the European Medicines Agency to learn from independent medication error reporting programmes in a complementary way with pharmacovigilance (§ no.4.2.6.2). Prescrire also specially urges the European Medicines Agency:
- to respect its obligations regarding transparency (§ no.5);
- to withdraw the new provisions concerning the umbrella trademark names for non-prescription medicinal products (§ no.2.4.4) and introducing the bypass, even “*exceptionally*”, of the Name Review Group (§ no.4.2.5/4);
and not to change the current Guideline (Release 4) regarding the abbreviations and the suffixes (§ no.2.3.1) and the names of fixed combination medicinal products (§ no.2.3.5).

SPECIFIC COMMENTS ON TEXT

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Paragraph no.	Comment and Rationale	Proposed change (if applicable)
§ no.2.1	**Asking for safety reviews of proposed trademark names by pharmaceutical companies.** According to the project, the EMEA expects from pharmaceutical compagnies that they "*review the proposed invented name, applying the criteria outlined in this guideline, before requesting that an invented name(s) be considered*" and provide "*detailed information addressing the above (…) within the invented name application form(s) or as part of a justification for retaining the invented name*". However, there is a variety of assessment methods that may be applied to identify if there are look- or sound-alike trademark or non-proprietary medicines names already registered which could be confused with a proposed trademark name, to take in account as well the contributing factors as the potential risk of health damage either due to the inadvertent administration of the medicine or the lack of administration of the intended medicine to a patient. No indication for selecting assessment methods is provided by the Guideline, even if methods are not yet scientifically validated and it is unclear which assessment method or which combination of methods will be the most relevant to predicting risks of look-alike and sound-alike medicines names.	**To provide better background regarding assessment methods for predicting risks of look-alike and sound-alike trademark names.** With a view to transparency, as a reference for auditing, and in order to help pharmaceutical companies, European healthcare practitionners and citizens, to anticipate the risk of confusing the names of medicinal products, the EMEA should: - ensure scientific validation and reproducibility of assessment methods for predicting the risks of confusion between trademark names of medicinal products, in order to further standardise them; - explicitly indicate the recommended assessment methods for this purpose, - return public those assessment methods which are employed by the Name Review Group. These assessment methods should comprise end-users tests by experts, healthcare practitionners and patients, in real world caring situations.
§ no.2.2.	**Addressing international nonproprietary names' concerns.** Release 4 of the Guideline stated: "*The EMEA will be monitoring outcome of the above policy very closely and review it as appropriate on a yearly basis*". The reasons of the abandonment of the principle of an annual review of the problems related to the similarities with DCI or their stems are not clarified.	

Paragraph no.	Comment and Rationale	Proposed change (if applicable)
§ no.2.3.1	**Dangerous retreat on the abbreviations and the suffixes!** The version in force of the Guideline disapproves the use of abbreviations and suffixes deprived of univocal significance, and regards them as "unacceptable" (See Release 4 §2.3.1). Possible exceptions, such as the description of the route of administration (for example: IV, IM, SC), must currently be the subject of a precise motivation from the applicant. At the opposite, the project considers that "*the use of qualifiers/abbreviations by letters as part of the invented name should in principle be acceptable*". Related to the duration of action, devices, patient population, such abbreviations and suffixes are officially intended "*to help the professionals of health and/or the patients to prescribe/select the drug*". In fact they offer new forms of publicity to the pharmaceutical companies who urged for this change. The example list of the acceptable abbreviations and suffixes is not yet established by the Name Review Group. Therefore, it is difficult to appreciate up to which point the European Medicine Agency intends to satisfy the recurring requests of the firms. Because the abbreviations and the suffixes are likely to cause medication errors, this change of position proves very dangerous for European patients.	**To control more strictly the abbreviations and the suffixes as part of the trademark names of medicinal products.** The EMEA should control more strictly the abbreviations and the suffixes as part of the trademark names of medicinal products because they are a frequent cause of medication errors. Have regard to the risks induced by this too important arrangement of the former Guideline, it is necessary to return to a more restrictive approach of the abbreviations and suffixes, to make the exception rather again than the rule, and to limit strictly their possible use. At least, not change should be introduced to the current Guideline (Release 4) because it is less dangerous.

Paragraph no.	Comment and Rationale	Proposed change (if applicable)
§ no.2.3.5	**Still more errors in prospect with the trademark names of fixed combination medicinal products!** Because "*EMEA has been reported medication errors on these type of medicinal products*", the trademark names of fixed combination medicinal products were asked in Release 4 to be "*completely different*" from the combination of the trademark name "*borne by the individual active substances of the fixed combination*". Surprisingly, this concern has been removed from the Release 5 with the result that from now it will be enough that they are "*sufficiently different*" from these trademark names or those of other associations comprising them. In the absence of evaluation by end-users in situations of care, this arrangement is extremely likely to lead the firms to propose only commercial names strongly evoking those already memorized by the prescribers. Whereas fixed associations are not often of clinical interest, it would be detrimental for the patients whom they provoke the additional risks of medication errors.	**To control more strictly the trademark names of fixed combination medicinal products.** The EMEA should control more strictly the trademark names of fixed combination medicinal products because they are a frequent cause of medication errors. At least, not change should be introduced to the current Guideline (Release 4), less permissive.

Paragraph no.	Comment and Rationale	Proposed change (if applicable)
§ no.2.4.4	**Surreptitious recognition of umbrella trademark names for non-prescription medicinal products** Not only, the trademarks names directly advertising to general public have more facilities to derogate from the constraints regardind the use of abbreviations and suffixes (see also our comment § no.2.3.1) or the names of fixed combination medicinal products (see also our comment § no.2.3.5), but especially the addition of complementary terms in the trademark name is allowed, alleging that it should be considered as "*instructions of employment*" to be introduced in the commercial name. However, these "*instructions of employment*" constitute only one of the labelling mentions to be made on the outer packaging in this precise case,according to Article 54(n) of Directive 2004/27/EC. Nothing authorizes the applicant to incorporate them in the commercial name. Over this specious reason formally disguished as a misunderstanding of Article 54(n) of Directive 2004/27/EC, the European Medicines Agency provides an implicit official recognition to umbrella names for non-prescription medicinal products. Prescrire is strongly opposed to umbrella names which, under the same name, expose the patients to medicinal products of different compositions and do not allow them any more to identify clearly the substances that they use.	**To withdrawn rules overmeasure for umbrella trademark names and restrict their use for non-prescription medicinal products** The European Medicine Agency should consider that an umbrella trademark name for a different combination of medicines with several active pharmaceutical ingredients may lead to confusion. Patients and professionals may not be aware of the difference, which may give rise to errors that can lead to unexpected consequences. Therefore, the European Medicine Agency is urged: - to withdraw these exemptions, not consistent with Directive 2004/27/EC, for non-prescription medicinal products from the standard evaluation of the trademark names of medicinal products, due to the medication errors which they would involve; - to launch an indeepth evaluation of the risks related to umbrella names of non-prescription medicinal products within the European Union, for better appreciating the opportunity for measures of restriction, even of prohibition, which the consumer protection should require.

Paragraph no.	Comment and Rationale	Proposed change (if applicable)
§ no.4.2.5/4	**Rejection by NRG/CHMP of a proposed invented name.** And when the pharmaceutical companies do not have their proposed trademark names accepted by the Name Review Group, they will have the ability to ask to the CHMP to slice. This new provision, although presented like exceptional, withdraws any authority with the decisions of the Name Review Group.	**To reinforce authority of the Name Review Group** Paragraph no.4.2.5/4 must be withdrawn because it distort the whole name review procedure integrity.
§ no.4.2.6.2	**Report of medication errors due to the trademark names of medicinal products.** The pharmacovigilance system and Periodic Safety Update Reports (PSUR), are the current sources of the European Medicine Agency on medication errors due to the trademark names of medicinal products. However, as specified in the guide of recommendations, medication errors due to the trademark names do not necessarily result in adverse effects (ADR), therefore not permit reporting into the pharmacovigilance system. Since the current project introduces particular rules regarding the trademark names of non-prescription medicinal products directly advertised to general public (see no.2.4.4), the patients should be authorized to report medication errors due to the trademark names directly to the European Medicine Agency. In order to promote Europe-wide standards for safe medication practices, the Council of Europe recommends to "share and disseminate data and strategies for prevention and risk reduction"* and "to ensure that all medication error reports related to its relevant missions, such as naming, labelling, packaging, advertising of medicinal products, are shared with the European Medicine Agency" by European medication error reporting system**.	**To facilitate reporting of medication errors due to the trademark names of medicinal products.** Healthcare practitionners and patients should be encouraged to report medication errors due to the trademark names of medicinal products, even whithout occurrence of an adverse effect. Procedures and specific reporting forms should be established by the European Medicine Agencies in order to provide a better insight on this type of medication error. In this field, the particular knowledge from volontary and independent medication error reporting programmes deserves to be taken into account by the European Medicine Agency, as recommended by the Council of Europe. The learning resulting from thorough analysis of the medication errors reported to these safe medication practices centres, and their proposals for prevention, should receive a particularly interest from the Name Review Group. * Council of Europe "Recommendation Rec(2006)7 of the Committee of Ministers to member states on management of patient safety and prevention of adverse events in health care" adopted 24 May 2006. ** Council of Europe Expert Group on Safe Medication Practices "Creation of a better medication safety culture in Europe: Building up safe medication practices" Preliminarily version available as from 19 March 2007: 257 pages.

Paragraph no.	Comment and Rationale	Proposed change (if applicable)
§ no.5	**Transparency is too weakly adressed, in contradiction with Article 126(c) of Directive 2004/27/EC.** Except statistical information on the outcome of the NRG review on proposed names, the minutes of the meetings of the CHMP are dumb on the trademark names of medicines prone to confusion. However, if one can understand that the names suggested by the companies are not revealed for reasons of protection of the patent rights, it does not have no reason there to hold secret the known medication errors due to confusions between trademark names of medicines. Not only it is about the strict application of the rules of transparency endicted by Article 126(c) of Directive 2004/27/EC (7), but any retention of information regarding a known risk of confusion between trademark names of medicines is harmful with the health of the European citizens. It means deliberately exposing them at these known risks while preventing their looking after from self protection. The current attitude is shocking, because contrary with the public healthcare mission of safety alarm entrusted to the European Medicine Agency.	**To make public the known risks of confusion between trademark names of medicinal products.** As a postmarketing surveillance regular working process, the basic precautions as regards the public health protection and the respect of Article 126(c) of Directive 2004/27/EC posted “transparency”, require: - to mention the medication errors due to confusion between trademark names of medicines reported to the EMEA in the minutes of the meetings of the CHMP; - to permanently hold up to date a list of the pairs of trademark names having been the subject of medication errors in the all European Union countries; - to make this list accessible on the EMEA web site; - and to broadcast safety alarms when adverse effects result from medication errors due to confusion between trademark names.

Please feel free to add more rows if needed.