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

COMMENTS FROM THE INTERNATIONAL NETWORK OF SAFE MEDICATION PRACTICE CENTRES
GENERAL COMMENTS
Committed to prevent medication errors and to contribute to safer care, the International Network of Safe Medication Practice Centres (INSMPC) aims to achieve the essential objectives stated in the "Salamanca Declaration to promote safe medication practices globally", to encourage and further the development of safe medication practice centres in all countries and to facilitate cooperation amongst them: http://www.intmedsafe.net/SalamancaDeclarationINSMPC.pdf
The prevention of medication errors related to similar medicines names requires both pre- and post-marketing strategies and involves drug regulatory agencies, pharmaceutical manufacturers, medication error reporting programmes, health care practitioners and patients. Pre-marketing strategies should aim at designing new drug names, which do not pose a risk for confusion with existing names and assess new names in a systematic and standardised approach for a potential to be confused with existing names. By this, medicines with a high risk of name confusion would not be placed on the market. Post-marketing strategies should aim at minimising errors occurring with medicines that are already on the market and comprise the implementation of specific practices that prevent errors due to name confusion and reporting and dissemination of experiences the aim of changing practices and thus reducing the risks of recurrence. Therefore the improvement of the EMEA's Guideline on the acceptability of names for human medicinal products processed through the centralised procedure towards more patient safety is wellcomed by the INSMPC.
The International Network of Safe Medication Practice Centres considers that it is important to: - update medicines regulations to require manufacturers to assess the risks of possible sound- or look-alike confusion between the new proposed proprietary names and existing medicines. This evaluation should be carried out by a standardised procedure, which should include user testing of prescription in oral and written communication, and an assessment by an expert panel using techniques based on "failure mode and effect analysis". - ensure that when medication errors are reported to the manufacturers and regulatory authorities, there is open disclosure, discussion and feedback regarding previous similar incidents and error analysis to identify contributory factors, root causes, and an action plan to prevent a recurrence. - promote sharing of medication error data handled by the medication error reporting systems in Europe with post-marketing monitoring centers, and establish a way or mechanism through which to channel this information to the EMEA. On the basis of these principles, the International Network of Safe Medication Practice Centres provides following comments on the Revision 5 of the EMEA Guideline CPMP/328/98:

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CRITERIA APPLIED WHEN REVIEWING THE ACCEPTABILITY OF PROPOSED INVENTED NAMES		
paragraph no.	**Comment and Rationale**	**Proposed change (if applicable)**
§ no.2.intro	**Safety reviews of proposed invented names by pharmaceutical companies.** According to the project, the EMEA expects from pharmaceutical companies 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*". Although it is unclear which assessment method or which combination of methods will be the most efficient to predicting risks of look-alike and sound-alike medicines names, some indication for selecting assessment methods should be provided in the guideline. The guideline also fails to indicate how this evaluation should be carried out by the agency groups. There is a variety of assessment methods that may be applied to identify look- or sound-alike commercial or non-proprietary medicines names already registered which could be confused with a proposed new invented name, but the most useful method comprises end-users tests by healthcare practitioners and patients, in real world care-giving situations. In addition, once the possible similar names are identified, a systematic evaluation by an expert panel should be carried out using procedures based on failure mode and effect analysis, in order to evaluate the possible risks of confusion, considering the factors that are actually listed in section 2.1.1 of the guideline.	**To provide better background regarding assessment methods for predicting look-alike and sound-alike risks.** With a view to transparency, as a reference for auditing, and in order to help pharmaceutical companies 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. Until the best method is established, it is important at least to include the necessity of a test, with healthcare practitioners and patients, to look for similarities of the invented names. In addition, a systematic evaluation by an expert panel should be carried out using procedures based on failure mode and effect analysis, in order to evaluate the possible risks of confusion and the potential for harm taking into account the factors listed in section 2.1.1. - provide adequate support for research on previous above matters and organise conferences to disseminate findings on the detection and prevention of the risks of confusion between trademark names of medicinal products; - make publicly accessible those assessment methods employed by the Name Review Group.

ADDRESSING OTHER PUBLIC HEALTH CONCERNS IN PROPOSED INVENTED NAMES		
paragraph no.	**Comment and Rationale**	**Proposed change (if applicable)**
§ no.2.3.1	**New management of the abbreviations and 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*". 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 manufacturers who asked for this modification. Because the abbreviations and the suffixes may lead to confusion and medication errors, this change of position could be hazardous to European patients.	**To address the need for safer abbreviations and suffixes as part of the commercial names of medicinal products.** The EMEA should control more strictly the abbreviations and the suffixes as part of the commercial names of medicinal products because they are a frequent cause of medication errors. No change should be introduced to the current Guideline (Release 4) for safety reasons.

ADDRESSING OTHER PUBLIC HEALTH CONCERNS IN PROPOSED INVENTED NAMES		
paragraph no.	**Comment and Rationale**	**Proposed change (if applicable)**
§ no.2.3.5	**Proposed invented names of fixed combination medicinal products** Because "*EMEA has been reported medication errors on these type of medicinal products*", the proposed invented names of fixed combination medicinal products were asked in Release 4 to be "*completely different*" from the combination of the commercial name "*borne by the individual active substances of the fixed combination*". 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. This may provoke additional risks of medication errors.	**To control more strictly the proposed invented 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, no change should be introduced to the current Guideline (Release 4), less permissive.

ADDRESSING PRODUCT SPECIFIC CONCERNS IN PROPOSED INVENTED NAMES		
paragraph no.	**Comment and Rationale**	**Proposed change (if applicable)**
§ no.2.4.4	**Proposed invented names for non-prescription medicinal products** The addition of complementary terms in the trademark name will be 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. This new disposition will contribute to widespread 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 favouring umbrella trademark names** The European Medicine Agency should consider that an umbrella trademark name for a different combination of medicines with several active pharmaceutical ingredients might 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 proposed invented names of medicinal products, due to the medication errors, which they might induce.

POST-AUTHORISATION ISSUES RELATED TO INVENTED NAMES		
paragraph no.	**Comment and Rationale**	**Proposed change (if applicable)**
§ no.4.2.6.2	**Report of medication errors due to invented names of medicinal products.** The pharmacovigilence system and Periodic Safety Update Reports (PSUR), are the current sources for the European Medicine Agency on medication errors due to the invented names of medicinal products. However, as specified in the recommendations, medication errors due to the trademark names do not necessarily result in adverse effects (ADR), therefore they are not reported to the pharmacovigilence system. 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**. * 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.	**To facilitate reporting of medication errors due to invented names of medicinal products.** Procedures and specific reporting forms should be established by the EMEA in order to provide a better insight on this type of medication error. EMEA should draw on experience from voluntary and independent medication error reporting programmes as recommended by the Council of Europe. The Name Review Group should pay special attention to the results of thorough analysis of medication errors reported to the safe medication practices centres, together with their proposals for prevention.

ADRESSING TRANSPARENCY		
paragraph no.	**Comment and Rationale**	**Proposed change (if applicable)**
§ no.5	**Transparency should be more aggressively addressed** The monthly CHMP report only includes statistical information on the outcome of the NRG review of proposed names, but information on the trademark names prone to confusion is lacking. One can understand that the names suggested by the companies are not revealed for commercial reasons, but there is no reason to hold secret the known medication errors due to confusions between trademark names. Implementing transparency requirements in Article 126(c) of Directive 2004/27/EC (7) is not the only issue. Indeed, failure to disclose information about a known risk of confusion between drug names may be harmful to European citizens. It means deliberately exposing them to known risks, which goes against the public health mission of the EMEA.	**To make public the known risks of confusion between invented names of medicinal products.** As part of postmarketing surveillance, public health protection and the respect of Article 126(c) of Directive 2004/27/EC on "transparency", require: - to report medication errors due to confusion between trademark names of medicines in the minutes of CHMP monthly reports; - to set up and permanently update a list of pairs of trademark names leading to medication errors in all European Union countries; - to make this list accessible on the EMEA web site; - and to circulate safety alerts whenever adverse effects result from medication errors due to confusion between trademark names.