15 March 2022

Submission of comments on Guideline on the acceptability of names for human medicinal products processed through the centralised procedure' (EMA/CHMP/287710/2014, Revision 7)

https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure_en.pdf

Comments from: PRESCRIRE

Name of organisation or individual
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Contact: Rita Kessler and Pierre Chirac (contact@prescrire.org or rkessler@prescrire.org)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	Prescrire welcomes several improvements to the previous guideline (Release 6): a stronger focus on the prevention of medication errors, the introduction of a preliminary assessment by firms, details provided about the assessment methods and criteria used by the Name Review Group (NRG). Another move in the right direction concerns a welcome opposition to umbrella names, to therapeutic promotion and claims, or to unpronounceable trade names. However, we have doubt that the completion of an application form is sufficient to seriously establish the risks related to names errors without providing strong assessment tools and methods. **Prescrire is worried by other aspects of this guideline, especially in terms of compliance with the directives binding on the European Medicine Agency (EMA) and marketing authorisation holders (MAH):** • **Regarding the respect of the International Non-proprietary Names (INN),** the EMA should encourage the use of INN-based brand names composed of the INN and the name of the company as first option, in example by: - making clear that the INN-based name should be the first 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.	

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	When this first option naming is not used, demand and check that the INN is more visible than the invented name on labelling. • **Regarding the independency of the EMA, getting involved in negotiations with companies for possible name's re-use or 'conditional acceptation', makes EMA seeming like a "trade name broker" on an unnecessary name recycling market.** **Stronger focus on preventing medication errors** The proposed guideline mentions several important points related to preventing medication errors: o Claim to "promote patient safety" (§2) o Following the consultation on the last revision in 2013 (CPMP/328/98 Revision 6), the EMA established its doctrine on the prevention of medication errors, with the publication at the end of 2015 of the 2014 Good practice guide on risk minimisation and prevention of medication errors (EMA/606103/2014) o The guideline refers to this 2014 guidance on medication errors (GPG), with a quote from the executive summary (p.5) which places securing the name of the medicine within the set of measures to secure the packaging of a medicine. However, the rules relating to names are only slightly developed, as they refer to the guideline of the time (§6.1.1.1. of this GPG) o Link established and confirmed with the assessment of packaging and legibility (§4.1.17), in accordance with §6.1.1.2 of this GPG, which notably encourages companies to avoid name confusions between medicinal products: *In addition to the review of names and packaging, MAHs and applicants should consider the appearance*	

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	and name of their medicinal product in comparison to medicinal products from other manufacturers used in similar indications, and the potential for confusion between medicinal products. (p.18) o Encourages companies to report to the Name Review Group (NRG), without prejudice to their pharmacovigilance activity, errors related to name confusion or to relay to the NRG any such information reported by an healthcare practitioner or identified in the course of their literature review (§6.7.2.1) **Introduction of a preliminary assessment by firms: guided only by filling out an application form** (Appendix 2 + application form) Welcome step, but should be strengthened by a detailed report, like required by the FDA or Health Canada o Encouragement to check for similarities (Appendix 2 checklist and extract from the EMA public database) o Assessment of similarities according to Appendix 2 (§6) o Encouragement to look at the risks of confusion with the brand names of devices and food supplements o Companies encouraged to consider the "life cycle" of their specialities and to have a prospective approach (§6.7) o The assessment is not only based on the elements provided by the company: the NRG allows itself to conduct extended searches... on the Internet, in particular for withdrawn brand names (§4.1.2)	

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	The EMA provides details on the assessment methods and criteria used by the NRG o Welcome consideration of conditions of use, drug care, professionals involved, patient characteristics, care and use settings (§4.1.1) o Consideration of trade names of associated devices (§4.1.14) o Welcome consideration of the human factor and cognitive biases in assessing the risk of error (§4.1.6) o Criticism against the lack of assessment by negligent companies §6.3: possibility of rejecting a sloppy application), but no evolution of the rejection criteria (§6.5) o Non-exhaustive list of criteria (Appendix 1) o Evaluation table (NRG checklist for assessment of objections on the basis of name similarities) (Appendix 2), presented in the introduction to §6 **There are still gaps in the methods of searching for phonetic and orthographic similarities (not technically detailed)** o Reference to the checklist in Appendix 2 o Reference to the EMA public database o No similarity search tool such as the FDA Phonetic and Orthographic Computer Analysis (POCA) Program o No clear criteria for accepted similarity levels, except for names including INNs (50%) for which this threshold is irrelevant o Persistence in accepting suffixes and abbreviations, despite recognised risks (§4.1.13)	

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	The EMA is moving in the right direction on some issues: o Strong opposition to umbrella names (§4.1.5, §4.1.11) o Strengthening of the framework against therapeutic promotion and claims (§4.1.8) o Refusal of unpronounceable trade names (§4.1.12) **But the EMA hampers the routine use of INN and discredits the use of the option INN+MAH name** Since the 6th revision the EMA's drug name review procedure became identical for all three types of name: invented names, the non-proprietary name followed by a trademark, and the non-proprietary name followed by the name of the MA holder. INN-based names are no longer be considered as "default options": a discouraging provision to use INN-based names. o Truncated quotation of Article 1(20) of Directive 2001/83/EC, as in previous guidelines, aiming to assimilate this legal possibility of naming to a promotional naming of the brand (§4.2), by mixing two quite distinct aspects in the previous guidelines: - the verification of compliance with international rules on compliance with the INN and key segments (contained in the former §4.2, l.313-334), - and special considerations for the use of the default INN + MAH name combination, mostly used for copies and generics (previously in former §4.3.6, l.335-377) o Distrust or even aversion to the use of the INN: • Rather than using the tools of the INN programme, inappropriate use of coefficients of similarity to detect INNs and stems in a trade name (50% rule), whereas the regulatory criteria are more precise: presence or absence	

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	of an INN or stem. This method does not allow for much more than tracking. • No incentive to request modified INNs when this is a relevant solution to improve differentiation between derivatives or formulations (§4.1.9) • Problem of common names not complying (l.351-354) with the recommended INNs due to lack of compliance with the rules for expressing concentrations in base rather than in salts: this case shows that the EMA is aware of the possibility of having the firm requesting a modified INN. • Same attitude in the specific case of biosimilars, using a reference to WHO guidelines (not verified, §4.3.5), to exempt itself from the application of the Directive o Explicit criticism of default names based on INNs: • Increased risk of selection error, especially in the case of fixed-dose combinations of substances (l.373-377) • Refusal to allow this type of name in the case of small packages (§4.1.17, l.296-299) **EMA's role and involvement as "trade name broker"** o Promoter of negotiations between companies with confusing trade names (§6.6) o Managing the obsolescence of trade names (§6.8: withdrawal, expiry) o Recycling of trade names already in use or submitted (§6.9)	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
62-66		This executive summary briefly lists the different points affected by a change, but does not give the reasons. A table of additions and modifications made available as an Appendix to this consultation would have made it easier to locate and analyse them.	
106-110		It was only after the consultation on the last revision in 2013 (CPMP/328/98 Revision 6) that the EMA established its doctrine on the prevention of medication errors, with the publication at the end of 2015 of the Good practice guide on risk minimisation and prevention of medication errors (EMA/606103/2014). Reference to this guidance is welcome, as the citation of its executive summary extends the consideration of the name to its use in packaging components, which is very important for the analysis of the practical risk of medication errors.	
112-114		Consideration of these categories is important because they may be OTC products previously authorised as medicines, usually at national level, which may be confusing in the case of umbrella ranges. The joint use of the brand names of the medicinal product and the associated devices can lead to confusion that is detrimental to patients (*).	

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		This encouragement from applicants is welcome; but if they don't do it, the NRG should provide it. • Prescrire Editorial Staff "Asthma and COPD: risk of confusion between the brand name of the drug and the brand name of the inhaler" *Prescrire International* 2021 ; **30** (231) : 270.	
115-118		Since the 6th revision the EMA's drug name review procedure became identical for all three types of name: invented names, the non-proprietary name followed by a trademark, and the non-proprietary name followed by the name of the MA holder. INN-based names are no longer be considered as "default options" a discouraging provision to use INN-based names. Proposed change: The EMA should instead encourage the use of INN-based names composed of the INN and the name of the company for example by: - making clear that the INN-based name should be the first 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.	

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		When this naming scheme is not used, demand and check that the INN is more visible than the invented name on labelling.	
126-127		Substantial and welcome clarifications to previous versions	
128		A claim consistent with the reference to the Good practice guide on risk minimisation and prevention of medication errors (EMA/606103/2014)	
151-152		It is useful to provide an indicative list of examples of similarity criteria. It would have been even more useful to provide a search tool, such as the Phonetic and Orthographic Computer Analysis (POCA) Program provided by the FDA (see our comment lines 473-477).	
155-157		Welcome clarification in the interest of the patients concerned	
158		Welcome clarification Proposed change: to be grouped with their practice context (line 165)	
162-164		Welcome clarification to be completed by an incentive to simulate these care settings	

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166-171		Welcome clarification to be completed by an incentive to simulate these care settings	
182-187		The EMA must not permit the reuse of brand names that have already been used, in order to prevent both medication errors and interference with pharmacovigilance signals in the event of the original drug causing adverse effects that emerge years after discontinuation. This criterion poses a risk to patient safety and may cause confusion that can lead to medication errors such as wrong drug errors and wrong drug information being consulted. Such case of brand names identical to or highly similar to brand names in other countries but containing different substances have been identified by Prescrire Editorial Team (Candazol°: sertaconazole in France, omeprazole in Greece) or abroad by the US FDA.* • Merchant L, Lutter R, Chang S "Identical or similar brand names used in different countries for medications with different active ingredients: a descriptive analysis" *BMJ Quality & Safety* 2020; **29** (12):988-991. Proposed change: Refuse the recycling of previously used brand names.	

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192-194		This criterion should be sufficient to prevent the EMA from interfering in 'bilateral negotiations' between firms that do not fall within its remit (see our comment lines 615-646)	
198-200		The EMA must not permit the reuse of brand names that have already been used, in order to prevent both medication errors and interference with pharmacovigilance signals in the event of the original drug causing adverse effects that emerge years after discontinuation. This criterion poses a risk to patient safety and may cause confusion that can lead to medication errors such as wrong drug errors and wrong drug information being consulted. Such case of brand names identical to or highly similar to brand names in other countries but containing different substances have been identified by Prescrire Editorial Team (Candazol°: sertaconazole in France, omeprazole in Greece) or abroad by the US FDA.* • Merchant L, Lutter R, Chang S "Identical or similar brand names used in different countries for medications with different active ingredients: a descriptive analysis" *BMJ Quality & Safety* 2020; **29** (12): 988-991. Proposed change: Refuse the recycling of previously used brand names.	

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201-202		This criterion helps to stop the proliferation of "umbrella" brands, i.e. ranges of medicines with very different compositions that have the same name. Prescrire strongly supports the prohibition of "umbrella" brands, in order to protect the patient. By this way patients will no more be exposed to the risk of medication errors and preventable adverse events. The French Medicines Agency share the same position supported by the national court of the 'Conseil d'Etat' to which the companies had appealed (*). • Prescrire Editorial Staff "France's supreme administrative jurisdiction confirms the importance of abolishing umbrella brands" *Prescrire International* 2020 ; **29** (216) : 165. • Prescrire Rédaction "Gammes ombrelles : vers leur arrêt sur initiative de l'ANSM" *Rev Prescrire* 2018 ; **38** (417) : 506-507. Proposed change: Criterion to be linked to §4.1.11 which it should immediately precede for greater consistency.	
203-206		Together with the attributes provided in Appendix 1, this new criterion related to the 'human factor' approach of medication errors is relevant in determining the degree of similarity of a proposed name.	

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		Proposed change: These methods of preliminary analysing of the risks of name confusion deserve more detailed description, such as those made available in North America by the FDA and Health Canada * • Food and Drug Administration, Center for Drug Evaluation and Research "Best Practices in Developing Proprietary Names for Human Prescription Drug Products. Guidance for Industry" December 2020; 42 pages. • Health Canada "Guidance Document for Industry - Review of Drug Brand Names" July 2, 2014 ; 44 pages.	
219-222		We agree with the rejection of any misuse of company names or trademarks in variations with positive connotations as strict compliance with the MAH name allows respecting the principle that the INN-based name should be the first option. 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. It is the solution adopted when the brand names proposed by a company are rejected (see 6.4 lines 566-568). Proposed change:	

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		It should be made clear that 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*". • "Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use " (Consolidated version on 26/05/2021, art. 1(20) not modified by the Directive 2004/27/CE) OJ 28 November 2001: L 311/73. Criterion to be linked to §4.1.10 which it should immediately precede for greater consistency	
224-228		Does the qualitative aspect concern provisions already taken by the EMA to modify the brand name, such as liposomal or pegylated liposomal forms of drugs ? In this case, it is up to the agencies to ask the MAH for requesting a modified INN to the WHO INN Programme, instead of including generic terms in a brand name. • EMA "Names of liposomal medicines to be changed to avoid medication errors" 31 July 2019 + "Change of name of liposomal medicines at high risk of medication errors" 26 September 2019 + "Email to Prescrire" 20 September 2019: 6 pages.	

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		• Prescrire Editorial Staff "Liposomal forms of drugs: now specified in the brand name, but no improvement to the INN" *Prescrire International* 2021 ; **30** (223) : 48. Proposed change: Line 226 is only applicable if a request of a modified INN by the MAH to the WHO INN Programme has been unsuccessful. Add "in the INN and" before "in the invented name" in order to put this verification in the remit of the NRG.	
229		We appreciate the fact that the EMA is asking the NRG to be stricter, by brandishing the threat of an objection sanctioning a deviation similar to that denounced in §4.1.8 (lines 220-222)	
232-237		This new criterion helps to stop the proliferation of "umbrella" brands, i.e. ranges of medicines with very different compositions that have the same name. Prescrire strongly supports the prohibition of "umbrella" brands, in order to protect the patient. By this way patients will no more be exposed to the risk of medication errors and preventable adverse events. The French Medicines Agency share the same position supported by the national supreme	

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		administrative jurisdiction of the 'Conseil d'Etat' to which the companies had appealed (*). • Prescrire Editorial Staff "France's supreme administrative jurisdiction confirms the importance of abolishing umbrella brands" *Prescrire International* 2020 ; **29** (216) : 165. • Prescrire Rédaction "Gammes ombrelles : vers leur arrêt sur initiative de l'ANSM" *Rev Prescrire* 2018 ; **38** (417) : 506-507. • ANSM "L'ANSM publie ses recommandations sur les noms des médicaments - Point d'Information" 22 février 2018. Accès site : https://archiveansm.integra.fr/S-informer/Points-d-information-Points-d-information/L-ANSM-publie-ses-recommandations-sur-les-noms-des-medicaments-Point-d-Information	
238-251		Together with the attributes provided in Appendix 1, the complements to this existing criterion related to the 'human factor' approach of medication errors is relevant in determining the degree of similarity of a proposed name. It is relevant to include the particular European approach of the different Member States languages. Proposed change:	

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		These methods of preliminary analysing of the risks of name confusion deserve more detailed descriptions, such as those made available in North America by the FDA and Health Canada * • Food and Drug Administration, Center for Drug Evaluation and Research "Best Practices in Developing Proprietary Names for Human Prescription Drug Products. Guidance for Industry" December 2020; 42 pages. • Health Canada "Guidance Document for Industry - Review of Drug Brand Names" July 2, 2014 ; 44 pages.	
252-274		As recognised in lines 255-257 and 273-274, abbreviations and suffixes are a source of confusion, and their use must therefore be strictly limited. It is high time the NRG drafts an illustrative list of acceptable abbreviations and suffixes. The use of abbreviations and suffixes must once more be the exception rather than the rule. Proposed change: Revert to more prudent use of abbreviations and suffixes	
275-283		The joint use of the brand names of the medicinal product and the associated devices can lead to confusion that is detrimental to patients (*).	

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		• Prescrire Editorial Staff "Asthma and COPD: risk of confusion between the brand name of the drug and the brand name of the inhaler" *Prescrire International* 2021 ; **30** (231) : 270. Proposed change: It is not sufficient to place the name of the device after the strength: a statement such as 'with', or 'to be used with' would help patients not to confuse the name of the device with that of the medicine.	
288-306		Extending the consideration of the name to its use in packaging components, is very important for the analysis of the practical risk of medication errors. However, we disagree with the systematic rejection of long names (lines 296-299), particularly when using the INN-based name because this principle should be respected as a first option; all the more important because the INN conveys build-in information on the medicine with pharmacotherapeutic informative common stems which is essential to its proper understanding and thus to the prevention of errors; and because the INN must, in any case, appear on the packaging. Proposed change: The size of the packaging should be adapted to the name of the medicine product, at least the INN.	

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307-310		Is it reasonable to require a different brand name for each indication, while the EMA itself asks MAH to anticipate the possible evolution of their medicine products (see lines 211-212 and 648-651)? Proposed change: New criterion to be withdrawn	
313-314		Because of this truncated quote, it is not clear that 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. It is the solution adopted when the brand names proposed by a company are rejected (see §6.4 lines 566-568). Proposed change: The full quote should be provided 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***". • "Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community	

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		code relating to medicinal products for human use ” (Consolidated version on 26/05/2021, art. 1(20) not modified by the Directive 2004/27/CE) OJ 28 November 2001: L 311/73.	
321-326		The choice of calculating coefficients of similarity to detect the presence of INNs or common stems in a trade name, by applying a threshold of 50%, which we do not understand how it was determined, is not the most suitable method for complying with precise regulatory criteria: presence or absence of an INN or a stem. A more efficient tracking is provided to the NRG and companies by the WHO INN programme as an API tool on the INN School website:	

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		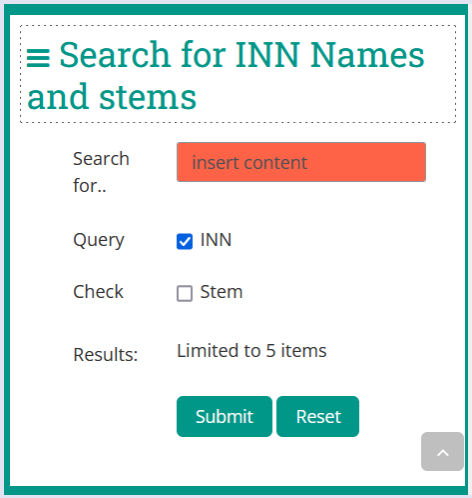 https://extranet.who.int/soinn/ Proposed change: Include the reference to the API tool developed by the WHO INN programme as on the INN School website: https://extranet.who.int/soinn/	
335-372		The combination in the same point of two aspects that were quite distinct in the previous guidelines: the verification of compliance with international rules relating to the respect of the INN and key segments (contained in the former §4.2,	

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		l.313-334), and special considerations for the use of the first option name of INN + MAH name, mostly used for copies and generics (previously in the former §4.3.6, l.335-377), is confusing as it introduces considerations for MAH names that have nothing to do with the INN and have already been presented in §4.1.8 (l.219-222). Proposed change: Clarify in a specific section related to the use of MAH names in the name of a medicinal product.	
351-354		This consideration is unclear as the concentration should be expressed as a base of the active substance rather than as a specific salt or derivative (or even not approved as a modified INN), otherwise there is a risk of medication errors as was the case with eribulin (Halaven°) * • Prescrire Rédaction "Halaven° : expression des doses clarifiée" *Rev Prescrire* 2012 ; **32** (349) : 826. Proposed change: item to be withdrawn due to uncertain legal basis	
373-377		As for the matter of too little packages (lines 296-299), we disagree with the systematic rejection of long names, even in the case or fixed combination medicinal products using the INN-based name because this principle should be respected as a first option; all the more important because	

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		the INN conveys build-in information on the medicine with pharmacotherapeutic informative common stems which is essential to its proper understanding and thus to the prevention of errors; and because the INN must, in any case, appear correctly in medication related software. Proposed change: The user interface of computer providing medicines names should be adapted to the name of the medicine product	
434-437		It seems curious to consider that the WHO Guidelines on evaluation of similar biotherapeutic product bypass the Article 1(20) of Directive 2001/83/EC Proposed change: item to be withdrawn due to uncertain legal basis	
457-459		In the absence of more precise criteria for this exemption, it seems worrying to expose patients to the consequences of possible dose-dependent errors. Proposed change: item to be withdrawn due to uncertain legal basis	
465-470		We agree with the importance of the invented name assessment, but the elements required by the assessment	

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		checklist do not seem to be sufficiently thorough to allow the NRG to make a decision. The MAH applicant should provide a more detailed assessment report, including names identified with similarity score of 50% or above, error reports available from clinical trials and published literature, and medication-use process simulations encompassing prescribing, transcribing, selection, dispensing, and administration, according to methods of preliminary analysing of the risks of name confusion, such as those made available in North America by the FDA and Health Canada * • Food and Drug Administration, Center for Drug Evaluation and Research "Best Practices in Developing Proprietary Names for Human Prescription Drug Products. Guidance for Industry" December 2020; 42 pages. • Health Canada "Guidance Document for Industry - Review of Drug Brand Names" July 2, 2014 ; 44 pages. Proposed change: Provide a more detailed methodological background to usefully assess the safety of proposed names	
473-477		The public raw data from Article 57 database is a basic source, but not easy to manage in order to identify eventual	

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		similarities. It would be even more useful to provide a search tool, such as the Phonetic and Orthographic Computer Analysis (POCA) Program provided by the FDA: https://poca-public.fda.gov/name_search Proposed change: Provide a comprehensive search tool	
487-490		The MAH applicant should provide a more detailed assessment report, including names identified with similarity score of 50% or above, error reports available from clinical trials and published literature, and medication-use process simulations encompassing prescribing, transcribing, selection, dispensing, and administration, according to methods of preliminary analysing of the risks of name confusion, such as those made available in North America by the FDA and Health Canada. Proposed change: Provide a comprehensive search tool, and request MAH to provide a detailed assessment report, including names similarities identified, error reports available from clinical trials and published literature, and medication-use process simulations at every stage of the medication use process, according to preliminary risk analysis assessment methods.	

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529-537		Rather than sanctioning firms that have not properly assessed the safety of the proposed name(s) by rejecting them, it would be better to provide a comprehensive search tool, and to ask them to form a detailed assessment report, including names identified with similarity score of 50% or above, error reports available from clinical trials and published literature, and medication-use process simulations encompassing prescribing, transcribing, selection, dispensing, and administration, according to methods of preliminary analysing of the risks of name confusion, such as those made available in North America by the FDA and Health Canada. Proposed change: Provide a comprehensive search tool, and request MAH to provide a detailed assessment report, including names similarities identified, error reports available from clinical trials and published literature, and medication-use process simulations at every stage of the medication use process, according to preliminary risk analysis assessment methods.	
572-577		Since the 6th revision the EMA's drug name review procedure became identical for all three types of name: invented names, the non-proprietary name followed by a trademark, and the non-proprietary name followed by the name of the MA holder. INN-based names are no longer be considered as	

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		"default options" a discouraging provision to use INN-based names. Proposed change: The EMA should instead encourage the use of INN-based names composed of the INN and the name of the company for example by: - making clear that the INN-based name should be the first 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.	
585-587		Seems to be duplicated in lines 593-595 Proposed change: To remove one of these occurrences.	
615-646		By presenting itself as a promoter of negotiations between companies with confusing trade names, the EMA seems a trade name broker and undermines its essential	

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		independence from the companies. Even if the EMA services and the members of the NRG do not participate in the actual negotiation between firms, they contribute to opening up a very specific service relationship whose legal regularity in relation to the EMA's mandate should be verified, particularly in the event of a dispute over the protection of industrial property. As stated in lines 195-196 "*only the 195 application which is granted a MA first may retain the (invented) name*". Proposed change: To be removed in order to protect the independency of the Agency.	
668-675		It is useful that companies are encouraged to report errors related to name confusion directly to the NRG, without prejudice to their pharmacovigilance activity, or to relay to the NRG any such information reported by an healthcare practitioner or identified in the course of their literature monitoring. However, medication error reporting programmes should be strengthened all over Europe in order to provide alerts and in-depth analysis of name related errors and to help healthcare practitioners and agencies to minimize them. Proposed change:	

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		It would also be valuable and welcome if the NRG, in collaboration with pharmacovigilance, were to make a regular review of the name confusion errors collected in this way and make it public with a particular attention to medication error reporting programmes.	
701-718		This part seems to correspond to the incorporation of the NRG position paper on the re-use of invented names of medicinal products (EMA/648795/2009 23 May 2011) into the guideline, which was not done in 2013 in the 6th revision. The EMA must not permit the reuse of brand names that have already been marketed, in order to prevent both medication errors and interference with pharmacovigilance. This criterion poses a risk to patient safety, as clearly stated lines 705-706. Cases of brand names identical to or highly similar to brand names in other countries but containing different substances may cause confusion that can lead to medication errors such as wrong drug errors and wrong drug information being consulted. They have been identified by Prescrire Editorial Team (Candazol°: sertaconazole in France, omeprazole in Greece) or abroad by the US FDA.* • Merchant L, Lutter R, Chang S "Identical or similar brand names used in different countries for medications with different active ingredients: a	

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		descriptive analysis" *BMJ Quality & Safety* 2020; **29** (12):988-991. Proposed change: In order to prevent any confusion, re-use of names of already marketed or granted for a marketing authorisation must be strictly forbidden. §6.9 and §6.9.1 (lines 693-718). should be removed accordingly.	