Overview of comments received on draft 'Guideline on the acceptability of names for human medicinal products processed through the centralised procedure' (EMA/CHMP/287710/2014 – Rev. 7)

Comments from: (165)

Stakeholder no.	Name of organisation or individual
1	EFPIA – European Federation of Pharmaceutical Industries and Associations (4+65)
2	EIPG – European Industrial Pharmacists Group (6)
3	Addison Whitney (1+2)
4	Prescrire (1+41)
5	INTA – International Trademark Association (1+5)
6	Gedeon Richter Plc. (3)
7	Gamida Cell Ltd. (2)
8	Drug Safety Institute (9)
9	ANEFP – Spanish selfcare association (1+4)
10	Novartis (1+8)
11	AESGP – Association of the European Self-Care Industry (1+10)

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1. General comments

Stakeholder number	General comment (if any)	Outcome (if applicable)
1 (Appendix 1)	Based on the goals of increased transparency and predictability of outcomes, we propose to convert the proposed language of Appendix 1 to a checklist format similar to that proposed (and used) in Appendix 2. Please see a draft proposal at the end of this submission document.	The introduction of Appendix 1 was intended to be indicative and highlight aspects of the name construction which could enhance similarity between names. The proposed conversion of Appendix 1 to a checklist is unwieldy and not in line with NRG objectives for its use. Although non-exhaustive, this list was considered as an additional element to take into consideration, in addition to other elements such as POCA, the multilingual check by the Member States (MSs), and the differences in healthcare systems across MSs, where reaching a harmonised approached may not always be possible. However, it is acknowledged that providing this level of detail without further explanations on how it will be used by the NRG and integrated into the remainder of the process may confuse more than clarify. Therefore, the Appendix 1 has been removed and integrated into the overall explanation of the NRG evaluation process. With regards to the Appendix 2, some of the remaining points from section 4.1.1. have been added to both the assessment checklist published, and the template used for the NRG discussion.
1 (Appendices)	We suggest introducing a scoring assessment for the elements at each of the Appendices in order to bring a level of objectivity to the exercise of considering all of the elements. Please see a draft proposal at the end of this document.	
1 (Introduction)	There is an inconsistent use of both *trade mark* and *trademark* in the document, we suggest standardising to *trade mark* in line with common European English.	Change accepted and implemented.

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1 (Throughout)	There is an inconsistent use of both *accepted invented name* and *approved invented name* in the document. We suggest standardising to accepted invented name.	Change accepted and implemented.
3	With 30 years of experience, and as a global branding agency with a strong capability in the name related causes of medication errors and their prevention, Addison Whitney applauds the efforts of the NRG to discuss proposed guideline updates with Interested Parties. We are honoured to be included in this endeavour.	General comment noted.
4 (6.1 submission requirements) (INN+MAH names)	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	The NRG considers, that the proposal for EMA to encourage the use of INN-based brand names composed of the INN and the name of the company as first option, is not acceptable for the following reasons:

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	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 first option naming is not used, demand and check that the INN is more visible than the invented name on labelling.	• In line with Article 1(20) of Directive 2001/83/EC, whereby the name of the medicinal product "may be either an invented name not liable to confusion with the common name, or a common name or scientific name accompanied by a trade mark or the name of the marketing authorisation holder", the NRG considers invented names and INN +MAH/TM names to be equal in status. • There is no evidence to support that such a change would result in a reduction of medication errors related to naming. • The use of INN+MAH names may have an impact on labelling, e.g. space constraints on small labels. • There may be cases where INN+MAH names are not considered appropriate, and create a divergence with other regions, also vis-à-vis the desire for global trade names. • The encouragement of INN+MAH names as a first option may be at odds with other regional approaches, such as the use of random 4-letter qualifiers in the US for biologicals. The NRG does not consider there is a need to create a different procedure for their review and approval. The NRG, however, will fast-track their review via written procedure if a CHMP Opinion is imminent, and no name has been obtained by the applicant. A decision to waive the variation fee when pharmaceutical companies decide to replace an invented name with an INN-

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		based name is not within the remit of the NRG nor the scope of the revision of this guideline, and would require a revision of Fee Regulation (EC) No 297/95. Lastly, it is within the scope of the mock-ups and specimens review to ensure that the information provided in the packaging is seen in the context of the complete product information and balanced in regards to the overall pack design.
(6.6 bilateral negotiations)	• **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.**	The EMA doesn't interfere but solely facilitate initial communication between the two parties if they both confirm their interest. The EMA is not involved further in the negotiation process. Aspects related to intellectual property rights and trademark registration are not considered by the NRG while reviewing the acceptability of a proposed (invented) name.
(avoidance of MEs)	**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 '' 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)	General comment noted.

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(6.1. Applicant assessment to be strengthened)	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 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	

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(More details on assessment methods and criteria) (Appendixes, Art 57, POCA)	searches... on the Internet, in particular for withdrawn brand names (§4.1.2) **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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(Positive: Umbrella branding, promotional aspects, pronunciation) (Negative: no routine use of INN+MAH names) 4.2 Inclusion of different INN aspects	**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 of an INN or stem. This method does not allow for much more than tracking.	The statement *'Proposals for invented names, as well as for names presented under the construction 'INN + company name/trademark', will be subject to EMA review. The latter case is not a default option in case no invented name for a specific product is accepted by the NRG.'* is not intended to discourage the use of INN-based names, but to highlight that these names also require review by the NRG, and cannot be implemented without a group acceptance. Generic names are given the same importance as brand names. The correct identification of the product is the ultimate goal. Generic names were never a default option, i.e. without review.

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Negative: 'trade name broker in bilateral negotiation)	• 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)	The EMA doesn't interfere but solely facilitate initial communication between the two parties if they both confirm their interest. The EMA is not involved further in the negotiation process. Aspects related to intellectual property rights and trademark registration are not considered by the NRG while reviewing the acceptability of a proposed (invented) name.
5 (Introduction; trade marks)	The International Trademark Association (INTA) would like to thank the European Medicines Agency (EMA) through its Name Review Group (NRG) for the opportunity to provide its views and comments on the draft revision of "*Guideline on the acceptability of names for human medicinal products processed*	General comment noted.

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	through the centralized procedure" "EMA/CHMP/287710/2014, Revision 7" issued by the (Invented) Name Review Group (NRG), in the frame of the Draft Consultation https://www.ema.europa.eu/en/guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure.(the "Guideline"). INTA is a global association of trademark owners and professionals dedicated to supporting trademarks and related intellectual property rights, to foster consumer protection and to promote fair and effective commerce. INTA's members are more than 6500 organizations from 185 countries. The Association's member organizations represent some 35,000 trademark professionals and include brand owners from major corporations as well as small- and medium-sized enterprises, law firms and non-profits. There are also government agency members as well as individual professor and student members. INTA wishes to put forward constructive views and comments on specific issues in connection with the above identified draft, as set forth below in this document. INTA is aware that the NRG was established by the Committee for Medicinal Products for Human Use (CHMP) to perform reviews of the (invented) names of medicinal products being assessed by the EMA. The role and mandate of the NRG is described in the Agency "*Mandate, objectives and rules of procedure for the Name Review Group (NRG)*" which specifically provides that "*The group is responsible for review of (Invented) Names requests for human products submitted via the centralised procedure - To review the Applicants'/Marketing Authorisation Holders' (MAH) proposed names for the centralised procedure, from a*	

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	safety/public health point of view". It is also specified that in the frame of its function, NRG is entitled to update the Guideline on the acceptability of names for human medicinal products processed through the centralized procedure. INTA has reviewed the proposed amendments to the draft "Guideline" and respectfully submits that a number of the proposed amendments **exceed the legal basis of the NRG which at Section 3 of the Guideline is stated to be in accordance with Article 6 of Regulation (EC) No 726/2004 and Article 1(20) of Directive 2001/83/EC, as amended, namely to require that each authorization application include *"a single name not liable to confusion with the name of another medicinal product."*** INTA believes elements of the Guideline as commented on below reach far beyond the scope of confusion between names of medicines. An assessment of whether a medicinal product name is liable to cause confusion with the name of another medicinal product should **not include subjective assessments**, for example whether the proposed product name is (on its own) **offensive**, **inappropriate** or **trivial**. Although the amendments to the Guideline include the proposed consideration of such factors (as discussed further below), **the amendments are overbroad, unclear and exceed the legal mandate of the NRG**. Further, as many of the terms comprising the proposed amendments are not defined in the Guidelines and criteria of assessment are not elucidated, the application of the proposed amendments will be **highly subjective and fraught** with uncertainty for applicants.	**Challenge to objections on the basis of offensive, inappropriate or trivial names.** ***Legal basis**: The EMA has established a review process performed by the NRG to ensure that the provisions set out in Article 6 of Regulation (EC) No 726/2004 and Article 1(20) of Directive 2001/83/EC are adhered to.* ***Criteria followed**: When reviewing the acceptability of proposed (invented) names, the NRG applies criteria based on public health concerns and in particular with regard to safety (see sections 4.1 and 6).*

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	It is INTA's view that the NRG assessments of "," (**offensive** Line 284) "**inappropriate**," (Line 284) and "**trivial**" (Line 218) are contrary to the principles of law supporting the freedom of expression of a trademark owner (see for example Article 19(2) of the International Covenant on Civil and Political Rights, and at the EU level, Art. 11 of the Charter of Fundamental Rights of the European Union as well as the Recitals (21) of European Union Trademark Regulation 2017/1001), unless they can be justified by the legitimate public health or safety objectives of the EMA. To be justified in respect of such objectives the restrictions must be both (1) proportional to the alleged harm which exploitation of the trademark owner's right is alleged to cause, and (2) on a balance of probabilities and based on compelling and credible quantifiable (scientific) evidence, be no more restrictive on economic value and use of the trademark than is necessary for the EMA to achieve its legitimate public health or safety objectives. These principles of requiring proportionality, compelling and credible evidence to support a restriction, and that the restriction be no more restrictive than is necessary have been adopted by INTA in a Board resolution on Brand Restrictions. **While the NRG does suggest that its decisions are based on "the best available evidence and research" (Line 111) what such evidence and research is, and how it is used to justify its subjective rejections of an Applicant's proposed invented name – the Applicant's trademark – is not provided.** Accordingly, in each instance as discussed below, these subjective elements ought to be deleted.	**4.1.15** The (invented) name of a medicinal product should not be offensive or have an inappropriate connotation in any of the official EU/EEA languages. Provision introduced in revision 4 of guideline (April 2005). At that time INTA commented the following "***INTA agrees with this*** *but urges that this should be a strong justification for allowing exceptions to the single trademark requirement. As previously stated, the present membership of twenty-five countries and numerous languages in the EU, requires increased flexibility in the enforcement of the single trademark requirement*." In EMA/HMA's view, the language proposed is proportional to the need to avoid using invented names that may be perceived as minimising the risks or encouraging an unreasonable consumption of the associated medicinal products. This restriction is proportional to the objective of protecting public health, and we see no conflict with the freedom of expression of a trademark owner, which has to be balanced against the general interests. When reviewing the acceptability of proposed (invented) names, the NRG applies criteria based on public health concerns and in particular related to safety. The proposed deletion of this criterion may leave the door open for not marketing the product in the Member State(s) concerned by the offensive/inappropriate connotation, which would jeopardise equitable access to medicines for all patients across the EU/EEA.
9	Brands are a great asset of companies, and studies, investments and projects that have important consequences are	General comment noted.

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	carried out on them. Companies promote the safe use of trademarks and seek consumer´s protection at all times avoiding any risk of confusion in the consumer or health professional.	
10 (Global names)	Novartis appreciates the recent revisions to the *NRG: Guideline on the acceptability of names for human medicinal products processed through the centralised procedure* which provide direction and greater clarity on several procedural and review-based methods. <u>General comment on global naming consistency.</u> As a matter of principle, Novartis generally strives for global uniformity of brands and we believe that consistency leads to greater benefit for patients, HCPs, and other stakeholders. This benefit includes clarity in the prescribing and medication use processes and packaging and labelling. Our request is for the NRG to accept the reasons for this preference and appreciate the difficulty involved in achieving a harmonised global brand name. Sponsors seeking global names face enormous challenges to identify a name that is legally available, attractive, linguistically appropriate around the world, and acceptable to health authorities such as the EMA which all conduct robust but methodologically different assessments of proposed names.	General comment noted. Provisions are already foreseen by the revision 6 towards flexibilities in case of constraints achieving a global (invented) name.
11 (Introduction of too many restrictions; avoidance of ME is	We observe that the guideline has been very much expanded from the last version and includes additional restrictions due to the potential risk for confusion and safety issues. It is more and more difficult to find invented names which are not in use and	General comment noted. Nevertheless, a number of measures have been introduced in this revision to specifically address such difficulties, e.g. decreasing the maximum validity period of

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multifactorial; umbrella branding support)	the number of new restrictions compared to the previous version makes this finding even more difficult. We contend that the name alone cannot bear the sole responsibility for confusion and errors.	invented names to 4 years (3 + 1), and encouraging applicants to re-use approved invented names.
	As recalled in lines 132-133, Article 1(20) of Directive 2001/83/EC, as amended, which require each authorisation application to include a single name not liable to confusion with the name of another medicinal product, a name`s potential to mislead must be based on a case by case evaluation of each proposed (invented) name. The mere inclusion of a common umbrella segment cannot as such be sufficient to characterize the liability of the name to create confusion. For that reason, it cannot be considered as not acceptable as a matter of principle.	Not endorsed. The use of a common umbrella segment across a range of products for the purpose of marketing unnecessarily increases the risk of confusion. Therefore, it may negatively affect the correct identification of the product.
	Non-prescription medicinal products are self-selected or can be recommended by a pharmacist. The name is the only element which can help the selection of the adequate product. The other elements on the packaging and the packaging livery itself all play a role.	General comment noted.

2. Specific comments on text

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
62-66 Executive summary	4	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.	Comment noted. The executive summary has been expanded to provide the reasons behind the update to the guideline. A summary table will be considered for future revisions.
93-97 Introduction (trade marks)	1	Comment: Regulation N° 207/2009 is no longer in force. It has been replaced by Regulation 2017/1001 Proposed change: According to Article 4 of Regulation (EU) 2017/1001 of the European Parliament and of the Council on the European Union trademark, an EU trademark may consist "of any signs, in particular words, including personal names, or designs, letters, numerals, colours, the shape of goods or of the packaging of goods, or sounds, provided that such signs are capable of distinguishing the goods or services of one undertaking from those of other undertakings"	Change accepted and implemented.
100 Introduction (trade marks)	1	Comment: There is a typo in the word 'sole', this should be 'solely' Proposed change (if any): The applicant/MAH is sole**ly** responsible	Change accepted and implemented.
102 Introduction (trade marks)	1	Comment: "appropriate authorities" is vague Proposed change (if any): change to: "appropriate trademark office"	Change accepted and implemented.

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106 – 111 Introduction (GVP medication errors)	1	Comment: A reference is made in lines 106-107 to "the Good practice guide on risk minimisation and prevention of medication errors." Presumably the NRG is referencing the EMA's final document EMA/606103/2014 "Good practice guide on risk minimisation and prevention of medication errors" (the "Good Practise Guide") which is Reference 8 (at line 806). It should be so specified. In addition, the Good Practise Guide defines "name" using the same language as the NRG, namely: "The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder." (TITLE I, Definitions, Article I, Section 20, the Good Practise Guide). Accordingly, it should be made clear that the Good Practise Guide only references the NRG regarding its name consideration role. Suggested change (if any): Line 107 insert footnote "8" after the word "errors." Line 110 delete the last word on this line, "this" and replace with "its." Line 111 insert "…of the name as defined by the Good Practise Guide…" after the word "…evaluation…"	The reference to the "Good practice guide on risk minimisation and prevention of medication errors" has been complemented with the EMA reference number. Reference to the guideline has been included. The editorial amendment to line 110 is accepted and implemented. The amendment to line 111 is not accepted; the name is defined as per Article 6 of Regulation (EC) No 726/2004.
106-110 Introduction (GVP medication errors)	4	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	Comment noted.

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		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.	
111 Introduction (GVP medication errors)	1	Comment: Please elaborate on what is considered 'the best available evidence and research.' Is the evaluation based on the data that is provided by the applicant or on data that is gathered by EMA? See also comment on line 151. Proposed change (if any): change to: "…best available evidence and research, examples of which are set out in Appendix 3." Introduce an Appendix 3 which sets out the types and categories of evidence and research the NRG relies on in making its decisions.	The mention of best available evidence refers to the data provided by the applicant, the analysis (e.g. phonetic and orthographic name similarity algorithm, internal review) performed by EMA during the evaluation, and the experience gathered in previous reviews. Additional information has been included.
112-114 Introduction (devices & food supplements)	4	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 (*). **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.	Comment noted.
112-114	11	Comment:	The lack of comprehensive listing for medical device and food supplement names is

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Introduction (devices & food supplements)		In light of the legal basis for this guideline (Article 1(20) of Directive 2001/83/EC) which require each authorisation application to include a single name not liable to confusion with the name of another medicinal product, the encouragement to consider potential confusion with names of food supplements and medical device is out of scope. In addition, the focus on these two product categories is not justified. In practice it would be impossible to execute given the absence of existing exhaustive listing of all FS and MDs names respectively on the EU market.	acknowledged. However, the emphasis is put on the correct identification of the medicinal product and the prevention of medication errors in the clinical setting of use, hence the possibility to raise comments for the attention of the applicant. This paragraph has been amended accordingly.
115 – 118 Introduction (INN names)	1	Comment: This text sets out proposals when using INN names. It requires use of INN and Company name. It uses a plus "+" sign but doesn't make clear until Line 365 that NRG does not allow a hyphen or any other punctuation between the INN and company name. Proposed change (if any): Provide a clear example of how NRG requires a nonproprietary and company name to be submitted. Insert at the end of sentence on Line 118: "Names submitted following this option must not contain any punctuation marks between the INN and company name, e.g., "INN Drug Co.""	Change accepted and implemented.
115 – 118 Introduction (INN names)	4	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-	Changes not accepted. The NRG considers that the proposal for EMA to encourage the use of INN-based brand names composed of the INN

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		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. When this naming scheme is not used, demand and check that the INN is more visible than the invented name on labelling.	and the name of the company as first option, is not acceptable for the following reasons: • In line with Article 1(20) of Directive 2001/83/EC, whereby the name of the medicinal product "may be either an invented name not liable to confusion with the common name, or a common name or scientific name accompanied by a trade mark or the name of the marketing authorisation holder", the NRG considers invented names and INN +MAH/TM names to be equal in status. • The is no evidence to support that such a change would result in a reduction of medication errors related to naming. • The use of INN+MAH names may have an impact on labelling, e.g. space constraints on small labels. • There may be cases where INN+MAH names are not considered appropriate, and create a divergence with other regions, also vis-à-vis the desire for global trade names. • The encouragement of INN+MAH names as a first option may be at odds with other regional approaches, such as the use of random 4-letter qualifiers in the US for biologicals.

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			The NRG does not consider there is a need to create a different procedure for their review and approval. The NRG, however, will fast-track their review via written procedure if a CHMP Opinion is imminent, and no name has been obtained by the applicant. A decision to waive the variation fee when pharmaceutical companies decide to replace an invented name with an INN-based name is not within the remit of the NRG or the scope of the revision of this guideline, and would require a revision of Fee Regulation (EC) No 297/95. Lastly, it is within the scope of the mock-ups and specimens review to ensure that the information provided in the packaging is seen in the context of the complete product information and balanced in regards to the overall pack design.
126-127	4	Substantial and welcome clarifications to previous versions	General comment noted.
128 (Scope)	1	Comment: Here it is stated that the main aim of the NRG is to promote patient safety. However, while this is an aim of the EMA, the role of the NRG is limited to the authority invested in the NRG via Article 6 of Regulation No 726/2004 and Article 1(20) of Directive 2001/83/EC. Proposed change (if any): Amend sentence at Line 128 to state: "The aim of the work of the NRG is to prevent confusion between the proposed invented name of a proposed medicinal product and	This paragraph has been amended to specify NRG scope.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		the common name, or a common or scientific name accompanied by a trademark of a marketed medicinal product or the name of the marketing authorization holder."	
128 (Scope)	4	A claim consistent with the reference to the Good practice guide on risk minimisation and prevention of medication errors (EMA/606103/2014)	General comment noted.
147 – 177 (4.1.1 and Appendix 2)	1	Comment: The aspects set out in 4.1.1 should track the elements set out in the NRG Checklist in Appendix 2. They should be consistent by using the same categories and wording. Proposed change (if any): Redrafting of Checklist in alignment with relevant aspects under section 4.1.1 (The proposed new Appendix 2 is aligned.)	Section 4.1.1 and Appendix 2 have been amended to further align terminology. A cross-reference to the Appendix is also included.
149-152 (4.1.1 and Appendix 1)	11	Comment: The definition of the "degree of similarity" is subject to interpretation and the annex I is extremely extensive and depending on the interpretation can very much restrict any new names. Again for non-prescription medicines in particular the name is only one of the elements used in the selection of the medicine. Proposed change: instead of annex I add fictitious examples or cases to aid in understanding 'degree of similarity'	For the sake of confidentiality, past cases cannot be mentioned. However, examples of attributes considered by the NRG in evaluating the degree of similarity between two invented names are included throughout the section 6.
150 – 152 (4.1.1 and Appendix 1)	1	Comment: Please elaborate on the methodology to check the 'degree of similarity'. How is the research and investigation of the attributes performed? Relying on which data? By whom? The Appendix 1 draft states this should not be considered an exhaustive list, yet these points are extensive and varied, and can	Change accepted and implemented: the EMA name similarity analysis process is now described under a new dedicated section (see section 6.2).

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		be considered highly restrictive. In addition, several of the bullet points could actually be considered distinguishing and would therefore offer differentiation in medication ordering such as CPOE (E.g. line 770 or 777). For example in reference to Line 781, a review of existing ISMP examples of actual errors concerning names with "similar letters in different order" revealed a root cause or basis beyond the similar letters contained in the invented name such as packaging. The guidance outlines name construct attributes taken into consideration in determining the degree of similarity of proposed invented names in Appendix 1, but it should be noted that much of the body of the guidance does relay the importance of packaging and labeling as well as general product profile characteristics and clinical use as key elements in their assessment. Therefore, what actual weight will be applied to the linguistic attributes listed in Appendix 1?	The Appendix 1 has been deleted, and relevant examples of attributes have been included throughout the section 6. The importance of other elements such as labelling and pack design is stressed in section 4.1.17 already. The appended NRG checklist has been amended slightly to clarify that these aspects are reviewed sequentially, and an explanatory note has been added to further detail the use of the NRG checklist.
150 – 152 (4.1.1 and Appendix 1)	10	**Comment**: Novartis welcomes the NRG checklist carried over from the current guidelines, as well as many of the ideas suggested in the EFPIA submission. However, we request that the NRG not regard such a checklist as prescriptive in determining the outcome of a name, but rather a tool that organizes and assists the NRG's larger discussion of context and factors related to the test product and existing medicine(s). This agrees well with the fact that much of the body of the Guidance relays the importance of general product profile characteristics, packaging and labeling to be considered in relation to the proposed invented name(s). We appreciate that NRG determinations are made on a case-by-case basis with a holistic view that addresses not only name similarity but the medication use processes for relevant products to develop an overall assessment of risk in real-world settings. To facilitate	

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		alignment, we urge the NRG to specify in the introductory text of Appendix 1 that the attribute list be used as a tool by applicants along with other tools such as POCA, and to approach their overall assessment comprising due diligence the same wholistic way. Regarding Appendix 1, as evidenced by real-world cases of medication errors related to name confusion, it is not a simple matter to predict which name pairs are likely to result in an error. Often quite similar names coexist safely without incident, while errors can occur between names with little obvious similarity. Several of the bullet points in Appendix 1 could more often be considered distinguishing and would, therefore, offer differentiation in medication ordering such as CPOE (E.g. line 770 or 777). For example in reference to Line 781, a review of existing ISMP examples of actual errors concerning names with "similar letters in different order" revealed a root cause or basis beyond the similar letters contained in the invented name such as packaging. The title and explanation for Appendix 1 states that these are additional attributes to be taken into consideration to determine the degree of similarity between the proposed invented name and existing medicinal product names, and goes further to say that this is not an exhaustive list. We assert this new section of the guidance is ambiguous for the applicant to interpret, and unwieldy to apply during the testing of invented names. It omits an explanation of how the attributes are to be assessed relative to one another and how the results of those assessments are to be synthesized to form an overall conclusion about when two names may be deemed confusingly similar. Conversely, it is not clear how if consideration of some of the 19 attributes results in a conclusion that the names are different along that attribute would help to mitigate the degree of similarity. Whereas Appendix 2 relaying the	

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		NRG Checklist outlines an organized approach for how certain factors pertaining to the setting, prescribing, dispensing, preparing, administering and monitoring can either contribute to risk or help to differentiate the two products of interest, no such framework is provided in Appendix 1. Twenty-five years ago, the analysis of name similarity was largely confined to comparing names on the basis of 2-letter and 3-letter sequences along the length of the words, the number of edit operations to change one name into the other, the 3-letter rule, etc. However, studies of real-world name confusion showed there were numerous instances that were poorly explained or predicted by those simple metrics. More metrics were added to compensate, and eventually a more sophisticated array of sound-alike and look-alike calculations ensued that eventuated in POCA. Again, studies of name confusion errors showed that a number representing sound-alike and look-alike degree of similarity were found to be insufficient in addressing similarity conferred by handwriting versus printing, so again the list of metrics was expanded. Over time, POCA was also updated to better optimize its description of similarity and categories of low/medium/high similarity were adjusted to better fit reality. However, a study by **Shah, Merchant, Chan and Taylor** at FDA showed that ISMP name confusion error pairs were better predicted by certain morphological characteristics of the two names being compared than by POCA, despite the expanded list of metrics and upgrades. This was helpful because it showed how when certain similarity characteristics are present they likely confer additive risk of confusion based on post-marketing reporting, not simply higher degree of similarity that may or may not be significant in real world practice. Regarding Appendix 1, there is no analog of a published study nor is there a framework to guide applicants about the relative weight of the attributes, or how they should be considered together. The nineteen attributes represent an extensive, diverse	

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		listing that is both overly restrictive and extraordinarily labor intensive if all are to be applied to each of dozens of existing medicine names that are identified for each invented name tested. **Proposed Changes** (If any): We urge the NRG to consider Appendix 1 only as tool for assessing name attributes that may add to risk of confusion as well as those that are differentiating for the proposed invented name versus medicine name(s), all placed in the larger context of discussing the factors in Appendix 2 and more. We also request the NRG to describe more specifically how they are using Appendix 1 to help assess similarity such that it will facilitate applicants' understanding about heuristics and priorities that can lead to an objection. Such information would be extremely helpful to ensure consistent application of an approach for both EMA and applicants, and facilitate more objectivity and transparency in decision-making. As it stands, the list of Attributes comprising Appendix 1 is extensive and restrictive.	
150 – 152 (4.1.1 and rejection)	1	Comment: Please include an obligation for an explanation on which basis an application is rejected.	This is already stated in section 6.5 Applicant/MAH communication and follow-up: '*After adoption by CHMP, the Applicant/MAH will be informed by the NRG Chair of the outcome of the discussion of the proposed (invented) name(s) for their medicinal product(s) together with the reasons and source for the objection(s) raised.'*
151-152 (4.1.1)	4	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).	Comment noted for future consideration. Please be informed that the EMA is in the process of developing its own phonetic and orthographic name similarity algorithm.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
153-154 (4.1.1 and rejection)	1	Comment: The NRG should make it clear that it will share the basis for rejection identifying the particular aspect(s) as set out in section 4.1.1 and the evidence (if any) in support. Proposed change (if any): Revise sentence at Line 153 to state: "When assessing the potential for such confusion, at least the following aspects are considered, and in any rejection of a proposed invented name the relevant aspects will be identified to the Applicant along with evidence in support, if any:"	This is already stated in section 6.5 Applicant/MAH communication and follow-up: '*After adoption by CHMP, the Applicant/MAH will be informed by the NRG Chair of the outcome of the discussion of the proposed (invented) name(s) for their medicinal product(s) together with the reasons and source for the objection(s) raised.'*
155 – 157 (4.1.1 & intended patient population)	1	Comment: Add also 'gender' as aspects that could influence the selection of the correct product. Proposed change (if any): Aspects which could … mental clarity, gender, etc.	Change accepted and implemented.
155-157	4	Welcome clarification in the interest of the patients concerned	General comment noted.
158 (4.1.1 & intended HCP)	4	Welcome clarification Proposed change: to be grouped with their practice context (line 165)	Change accepted and implemented; a clarification has been inserted.
158 (4.1.1 & intended HCP)	11	Comment: we do not understand the addition of the HCPs as elements to be considered in the potential for confusion. Proposed change: remove or clarify what is meant here.	
162-164 (4.1.1 & complexity of handling)	4	Welcome clarification to be completed by an incentive to simulate these care settings	Comment noted.
162	11	Comment: similarly to the above comment, we do not understand how this elements - complexity of the product handling, e.g.	Comment partially accepted. Complexity of product handling would involve several controls

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
(4.1.1 & complexity of handling)		instruction for use and environmental aspects, e.g. storage - can lead to confusion. Proposed change: remove	and entail extensive checking which ultimately may mitigate the risk of confusion. This bullet point has been amended to improve clarity and understandability; reference to 'environmental aspects' has been deleted.
164 – 165 (4.1.1 & setting of use)	1	Comment: Storage conditions for products is another attribute worth mentioning. It is already identified in the NRG checklist at Appendix 2 Proposed change (if any): Add storage conditions at Line 165: "…dispensing, preparation (if applicable), storage conditions, and use/administration;…"	Storage conditions are considered while reviewing the possible risk at dispensing level (see Appendix 1).
166 – 167 (4.1.1 & controls)	1	Comment: Add also 'monitoring', since it is important to continue exercising safety control after a product is dispensed. For example, a product which will be administered by intervenious infusion requires careful safety control after the product is dispensed. Proposed change (if any): … prescribing, dispensing, preparation, administration or monitoring which …	Not endorsed. The safety monitoring of patients after administration of the medicinal product is out of the scope of the NRG name similarity analysis. The existence of product management process controls is considered separately (see Appendix 1).
166-171 (4.1.1 & controls)	4	Welcome clarification to be completed by an incentive to simulate these care settings	Comment noted.
178-188 (4.1.2)	1	Comment: This section states that NRG will consider a proposed invented name against revoked/withdrawn medical products. If a drug is in use in one member state but withdrawn in another, then it is appropriate for NRG to consider the proposed invented name against that drug's name. If a previously existing drug is revoked	Comment partially accepted and implemented. A similarity assessment will take place only if there is still a valid MA in one of the EU Member States.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		or withdrawn and not available in any member state, there would be no safety issue. Proposed change (if any): NRG should not include a comparison with names of unavailable medicines and delete ' revoked/withdrawn medicinal products'.	If there is no valid MA, the 5-year sales off period should be respected unless the applicant can prove the sales-off period has expired. The statement regarding a potential expansion of the 5-year period due to serious safety concerns has been removed, as the NRG is not best placed to confirm by how much this would be extended. It is understood that, in cases of serious safety concerns, the marketing authorisation holder (MAH) would immediately recall all existing batches; effectively there would not be a risk as the product would be taken off the market relatively quickly. Also, no MAH would want their medicinal product to be associated with a product withdrawn for serious safety reasons. Section 4.1.2 has been updated accordingly.
182-187 (4.1.2 & re-use)	4	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°:	See response to same comment on lines 701-718.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		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.	
182-187 (4.1.2)	9	Comment: It should be taken into account the possibility of using the name by another medicine that has the same composition of active ingredients and in that situation it shouldn´t be necessary to allow 5 years to elapse. Proposed change (if any): When considering the potential for confusion with the name of a withdrawn/revoked medicinal product, a period of 5 years should have, in principle, elapsed after the official invalidity of the MA**, except if the name is used by other medicinal product with the same composition in active ingredients**. This period could be reduced if it can reasonably be justified by the applicant/MAH, or extended in the case of withdrawal due to serious safety concerns, at the discretion of the NRG. In making these decisions the NRG may also take into account other aspects such as the	This would fall under the scope of a re-use application (see section 6.10.1). In case the applicant is different from the initial one, a proof of agreement between the two parties should be provided.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		existence of online information regarding the withdrawn medicinal product.	
186 – 187 (4.1.2)	1	Comment: 'online information' should be restricted, since the online information must still be relevant and trustworthy. Proposed change (if any): … existence of recent and comprehensive online information … or "...such as the existence of valid and verifiable online information regarding the withdrawn medicinal product."	This statement has been further substantiated as follows: *"In making these decisions the NRG may also take into account other aspects such as the existence of online information regarding the withdrawn medicinal product**, which patients may have access to through the internet**."*
192-194 (4.1.3 & bilateral negotiations)	4	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)	See response to similar comment on lines 615-646.
198-200 (4.1.4 & re-use of names)	4	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	See response to same comment on lines 701-718.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		different active ingredients: a descriptive analysis" *BMJ Quality & Safety* 2020; **29** (12): 988-991. Proposed change: Refuse the recycling of previously used brand names.	
201 – 202 (4.1.5)	1	Comment: This rule should be interpreted proportionately and not strictly, because many names are so short that it cannot be prevented to include them in a longer name. Several examples of names which wholly incorporate other names and appear able to safely coexist in the EU without likely confusion or error are: • Indimacis 125 (igovomab) coexists with Maci (Autologous Human Chondrocytes) • Genasense (oblimersen) coexists with Nasen (zolpidem tartrate) • Alisade (fluticasone), Sarclisa (isatuximab) and Heplisav B (hepB vax) coexist with Lisa (dienogest/ethinylestradiol) • Selincro (anlmefene) and Phelinun (melphalan) coexist with Elin (ethinylestradiol/norgestimate) • Kixelle (insulin aspart) coexists with Ixel (milnacipran) • Ixiaro (JAV vax), Lixiana (edoxaban) and Refixia (nonacog beta pegol) coexist with Ixia (olmesartan) • Other examples can be provided on request Proposed change (if any): Add: 'Exceptions may apply where the potential for confusion between the names is less than high similarity in print, speech and handwriting based on criteria appearing in Appendix 2.'	Change accepted. The following rephrased statement has been introduced to grant flexibility: 'Exceptions may apply on a case-by-case basis depending on the potential for confusion and the level of similarity identified.'
201-202 (4.1.5)	4	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	Change accepted and implemented. Cross reference to 4.1.5 from 4.1.11 included.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		"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.	
201 – 202 (4.1.5)	10	**Comment**: The Article 57 listing of products approved in the EU contains a large number of names which are also included in full in other, longer names, including centrally approved products and products coexisting in individual countries. While a short name may be memorable and distinct on its own, when included in a longer name it may become simply a string of letters which are subsumed within the identity of the longer name. In addition, this section also conflicts with a common and communicative naming strategy for combination product naming, for example where Actelsar HCT and MicardisPlus clearly provide useful information to patients and HCPs about the fact that each is a combination product based on the single-ingredient products Actelsar and Micardis.	Change accepted. The following rephrased statement has been introduced to grant flexibility: 'Exceptions may apply on a case-by-case basis depending on the potential for confusion and the level of similarity identified.' However, the use of qualifiers is out of the scope of this criterion – see section 4.1.13.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		Proposed change (if any): We ask that the rule be interpreted proportionately and not strictly, because many names are so short that it cannot be prevented to include them in a longer name. Add "Exceptions may apply where the potential for confusion between the names is low, for example where a shorter name is not notably recognizable when included as a mere letter string in a longer name. Additional exceptions may apply where there is communicative benefit in the inclusion of another product name, for example for combination products or for new dosage forms of an existing active ingredient where a new MAA is required."	
203 – 206 (4.1.6 cognitive error) 781 – 782 (Appendix 1)	1	Comment: This base of rejection is too vague and not based on objective criteria and thus should be deleted: The proposed rule relates to circumstances where the human brain may make perceptual connections between two names of medicinal products where there are not necessarily shared letters in the same order. This places the basis for objection entirely in the realm of cognitive experience, which is subjective, speculative, and unpredictable. There are no known objective criteria applicants may use to determine whether the human mind will make a connection leading to confusion where it is not based on demonstrable name similarity. Proposed change (if any): We request removal of this rule section 4.1.6 Instead, we propose to rely on "similar spelling" attribute at Line 762 of Appendix 1.	Proposed change not accepted. This new criterion is based on the experience accumulated since the last revision. At least a medium degree of similarity in print, speech and handwriting is endorsed when two invented names share the same letters in a different order.
203 – 206 (4.1.6 cognitive error)	10	**Comment**: This base of rejection is too vague and not based on objective criteria and thus should be deleted: The proposed rule relates to circumstances where the human brain may make perceptual connections between two names of medicinal	

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
781 – 782 (Appendix 1)		products where there are not necessarily shared letters in the same order. This places the basis for objection entirely in the realm of cognitive experience, which is subjective, speculative, and unpredictable. There are no known objective criteria applicants may use to determine whether the human mind will make a connection leading to confusion where it is not based on demonstrable name similarity. **Proposed change** (if any): We request removal of this rule section 4.1.6 Instead, we propose to rely on "similar spelling" attribute at Line 762 of Appendix 1.	
203-206 (4.1.6 cognitive error)	4	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. 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.	Change accepted and implemented; the EMA name similarity analysis process is now described under a new dedicated section (see section 6.2).

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
203-206 (4.1.6 cognitive error)	5	**Comment:** Proposed section 4.1.6 provides that "In some cases, even though two invented names do not share the same letters in the same order, the NRG may consider that the potential confusion is related to the way the human brain perceives them; this is considered as a cognitive error associated to at least a medium degree of similarity in print, speech and handwriting." INTA believes that the proposed section is highly ambiguous, subjective, impossible to predict, and contradicts Section 1 (lines 110-111): "The NRG performs this evaluation on the basis of best available evidence and research." The issue is how NRG could determine the way the human brain perceives names. Flowing from this is the question of whether NRG has personnel trained to know exactly how the human brain perceives a trademark or a medicine name and how that human perception can be evidenced or reproduced or predicted in an accurate way. INTA considers that such measure will not achieve the NRG's objective to protect consumers from confusion between a proposed invented name and a marketed medicine's name, on the contrary it will arbitrarily limit their right to choose between brands. This type of restriction is contrary to the principle of acquired trademark rights, since they are limiting or preventing the use of a trademark properly registered before the corresponding trademark office or offices. INTA considers that this type of prohibition based potential confusion should be made by the competent authority in charge of trademark registration that has the training and knowledge to do so. To do this after a granted trademark registration is to violate the right to use an asset that belongs to the owner of the trademark. It is a severe erosion of the brand value. **Proposed change (if any):** Delete Section 4.1.6.	Proposed change not accepted. The NRG's main role is to consider whether proposed (invented) names could create a public-health concern or potential safety risk. It is part of EMA's role in evaluating the safety of medicinal products. Aspects of intellectual property rights and trademark registration are not taken into consideration while reviewing acceptability of proposed (invented) names. Based on the experience acquired since the last revision, the NRG established in several occasions that two invented names with the same letters in different order are associated with a significant risk of confusion.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
207-212 (4.1.7 misleading therapeutic connotations)	11	Comment: it is understood but also in practice difficult to ensure taking into account all the EU languages.	Comment noted.
209 – 212 (4.1.7 misleading therapeutic connotations)	1	Comment: 'and/or mechanism of action' should be taken out because it is too restrictive. Proposed change (if any): … inclusion of elements related to the therapeutic indication ~~and/or mechanism of action~~ of the medical product …	Proposed change not accepted. Although correct upon initial marketing authorisation, subsequent therapeutic indications may be related to different mechanism of actions or pharmacotherapeutic effects, hence creating discrepancies between the product name and the product profile.
214-218 (4.1.8 promotional use)	11	Comment: the addition of 'overly fanciful' remains very subject to interpretation.	Not endorsed. The expression 'overly fanciful' is explained thereafter.
214 – 222 (4.1.8 promotional use) 215	1	**As to Art. 4.1.8** Comment: New Art. 4.1.8 is former Art. 4.1.6 but it seems to include also parts of former Art. 4.1.3. The first sentence is identical. The second sentence is similar to first paragraph on page 16 of the FDA 2020 best practice document. The issues described in this second sentence should not materialize with artificial names. This sentence includes the term 'overly fanciful'. Since the term 'overly fanciful' is very subjective it should be taken out of the guidelines.	Proposed changes not accepted. The expression 'overly fanciful' is explained thereafter.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
218		It is unclear to us when a name becomes 'trivialising' or how trivialising (whatever that means) is relevant to safety and confusion between drug names. The meaning could be interpreted subjectively. We suggest to delete this sentence. Proposed change: We suggest to delete this sentence at line 218	This sentence constitutes an important aspect of the NRG definition of a promotional message. "Trivialising" the invented name of a medicinal product is a particularly inappropriate behaviour which would endanger principles such as the reasonable use of medicines, in accordance with the approved indications and related warnings on the risks for the patients.
219		As to the third paragraph of Art. 4.1.8, first sentence (line 219 to 221): this situation is very unlikely. The likelihood of INN + company name being misleading or promotional should be rather low. Furthermore, this provision could be understood as if EMA could prohibit the use of the company name by companies. It is also somehow contradictory to the sentence in lines 607 and 608 where it is stated that if no invented name is accepted before adoption of CHMP opinion, the opinion will be adopted under the INN + company name. Therefore, we wonder whether this sentence should be deleted.	This new provision aims to cover cases where, e.g., the company name could mislead in terms of endorsement by a competent authority; also, when the name of the company may lead to promotional/misleading connotations when combined with the therapeutic indication. If so, an invented name should be considered.
221		Also the second sentence of third paragraph of Art. 4.1.8 (lines 221 and 222) should be deleted. This provision would constitute a strong limitation for companies to adopt a company name. If a company would adopt a new company name, would it then have to ask EMA before its adoption? What if, for instance, two companies merge together and give such a new company a new name. Should EMA have a say here? It is unclear to us what is meant by 'the trend to create MAH names variations with positive connotations'. We suggest to clarify or delete this sentence.	Deletion accepted and implemented. In such scenario, we trust companies would choose a name which doesn't affect the safe and effective use of their products.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		Also we suggest to only keep the sentence that the MAH name should not be ambiguous. Proposed change: To take out the term 'overly fanciful' To add examples of what is meant by 'trivialising' To take out sentences 219 until 221 and keep only the sentence that an 'MAH name should not be ambiguous'.	The proposed deletions are not accepted for the reasons set out above.
218 (4.1.8 promotional use)	5	**Comment:** INTA believes there is no legal or factual nexus between the wholly subjective assessment of "trivialize" and the decision of whether a proposed invented name is not liable to confusion with the name of another medicinal product. INTA repeats its comments set out at Line 284-284 below as they apply equally in respect of this proposed evaluation. **Proposed change (if any):** Delete line 218.	Proposed change not accepted. This sentence constitutes an important aspect of the NRG definition of a promotional message. "Trivialising" the invented name of a medicinal product is a particularly inappropriate behaviour which would endanger principles such as the reasonable use of medicines, in accordance with the approved indications and related warnings on the risks for the patients.
219 – 221 (4.1.8 promotional use)	2	Comment: In using INN + MAH, how could this be promotional or misleading? It is better to clarify what is meant by these lines Proposed change (if any): /	This new provision aims to cover cases where, e.g., the company name could mislead in terms of endorsement by a competent authority; also, when the name of the company may lead to promotional/misleading connotations when combined with the therapeutic indication. If so, an invented name should be considered.
219-222 (4.1.8 promotional use)	4	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	It is up to the applicant to choose between the two options foreseen by the EU legislation.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		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: 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	The proposed change to move the criterion related to similarity/allusion to the name of the MAH is accepted and implemented (paragraph 4.1.10 becomes 4.1.9 and vice versa).
223 – 228 (4.1.9 misleading pharmaceutical connotations)	1	**As to Art. 4.1.9** New Art. 4.1.9 (corresponds partly former Art. 4.1.2). The examples starting with "such as" are new and also the second paragraph. The first sentence of the second paragraph (line 226) does not make sense since it is evident that EMA will do anyway what is described there. It the purpose of this guideline. The second	Comment accepted; this paragraph has been reworded for further clarity.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		sentence of the second paragraph (lines 227 and 228) goes too far. One cannot always foresee all post-authorization changes. What are these changes? What would be a discrepancy?	
224-228 (4.1.9 misleading pharmaceutical connotations)	4	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. • 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.	Not applicable. This criterion refers to scenarios where pharmaceutical aspects (e.g. pharmaceutical form, prolonged-release properties) are reflected somehow in the proposed invented name and aims to prevent future potential discrepancies between the invented name and the product profile throughout the product life cycle.
229 – 231 (4.1.10 invented names which are similar or allude to the name of	1	**As to Art. 4.1.10** Further clarification is necessary, especially on what is meant by 'confusion at the level of product information' and 'to the name of	Comment accepted; this paragraph has been simplified for further clarity.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
pharmaceutical companies)		pharmaceutical companies'. What is the scope of companies that are meant here? Does it refer to the name of the MAHs of the product or the name of other pharmaceutical companies with no link with MAH ? One could ask whether EMA starts to enter the field of assessment of IP rights. How likely will it be that a company allows that another company registers a trademark which contains elements of the first company's name. For instance, would Novartis allow a third party to market a product under a trademark with the prefix "NOV-" ? Furthermore, what will EMA consider as similar? If the prefix of the company name and the trademark are identical or confusingly similar (would for instance, "BAY" and "BAI" or "NOV" and "NOF" be regarded as to similar ?) How about if the trademark contains the prefix of a third party' company name as an infix or suffix? Finally, concerning "…if they are thought to be misleading…or cause confusion at the level of product information." The "thought to be" and "allude" is too vague and subjective. If this is to be kept, it should revert to the previous wording and provide a caution, namely: "The NRG also considers invented names which are similar or allude to the name of pharmaceutical companies if they are thought to be misleading and cause confusion at the level of product information." If this is to be a basis to reject, it should use the same kind of factors as set out Lines 214-217. Proposed change (if any): Delete Lines 229-231. We prefer that language which provides notice be inserted at line 229 as follows: "The NRG will advise the Applicant if it considers invented names	The review of trademarks is outside the remit of the EMA. The NRG doesn't take into consideration aspects of intellectual property rights/trademark registration within the name review process. This remains a matter of similarity assessment, taking into account distinctiveness and evidence of the allusion. Comment accepted and implemented; this paragraph has been simplified for further clarity.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		which are similar or allude to the name of pharmaceutical companies if they are thought to be misleading and cause confusion at the level of product information." Although less preferred, if this is to be maintained as a basis for rejection then on line 231, immediately after "…product information" the following is inserted: "unless proof of trademark registration, such as a registration certificate of the proposed invented name in the EU is provided.	The proposed change is not acceptable since the review of trademarks is outside the remit of the EMA.
229 (4.1.10 invented names which are similar or allude to the name of pharmaceutical companies)	4	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)	Comment noted.
232 (4.1.11 umbrella branding)	1	Comment: It could have unintended consequences to prohibit a common umbrella segment, because this term could be applied too restrictively. Instead, it should be limited to the name of the sponsor. Some 'umbrella' concept names are specifically helpful with certain related products, for example Rasilez (aliskiren), Rasilamlo (aliskiren/amlodipine) and Rasitrio (aliskiren/amlodipine/hydrochlorothiazide) clearly assist HCPs and patients to differentiate between related products. Proposed change (if any):	Not endorsed. While the inclusion of a segment of the sponsor name is considered as the most common example of umbrella branding, it is not limited to this option. Forms of umbrella branding linked to other aspects (e.g. composition of active substances) will be considered on a case-by-case basis.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		The inclusion of ~~**a common umbrella segment (e.g.**~~ part of the name of the sponsor within the invented names of different medicinal products is not acceptable …	
232 – 236 (4.1.11 umbrella branding)	2	Comment: It would be useful to add an example Proposed change (if any): /	Change accepted and implemented. Examples of forms of umbrella branding have been included.
232-237 (4.1.11 umbrella branding)	4	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 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-	General comment noted.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		ANSM-publie-ses-recommandations-sur-les-noms-des-medicaments-Point-d-Information	
232 (4.1.11 umbrella branding)	10	**Comment**: Novartis' concerns relate to the potential for misapplication of this text, which appears to be drafted to address the use of parts of sponsors' names, but may end up extending to the rejection of names that are perfectly appropriate. For example, some 'umbrella' concept names have been shown to be specifically helpful with certain related products, for example Rasilez (aliskiren), Rasilamlo (aliskiren/amlodipine) and Rasitrio (aliskiren/amlodipine/hydrochlorothiazide) clearly assist HCPs and patients to differentiate between related products. **Proposed change** (if any): "The inclusion of a common umbrella segment within the invented name that is the name of the sponsor or represents it in some fashion can create a link in subsequent instances that may lead to confusion and medication errors. The use of an umbrella segment related to the Sponsor's name, unless the portion used is significant and evident when the name is considered as a whole, may however, be accepted the first time it is proposed for an invented name. The NRG will not accept the use of the same Sponsor's name segment in a second instance, constituting a common umbrella segment."	Not endorsed. While the inclusion of a segment of the sponsor name is considered as the most common example of umbrella branding, it is not limited to this option. Forms of umbrella branding linked to other aspects (e.g. composition of active substances) will be considered on a case-by-case basis.
234 – 237 (4.1.11 umbrella branding)	8	Comment: Reference to umbrella segment requires further clarification, as the concept of umbrella applies to 2 or more occurrences. Unclear whether it refers specifically to the name of the sponsor in this case. Proposed change (if any):	Further clarification added.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		The use of **parts of the name of the sponsor**, unless the portion used is significant and evident when the name is considered as a whole, may however, be accepted the first time it is proposed for an invented name. The NRG will not accept the use of the same segment in a second instance.	
232-237 (4.1.11 umbrella branding)	9	Comment: "*The inclusion of a common umbrella segment (e.g. part of the name of the sponsor) within the invented names of different medicinal products is not acceptable as it creates a link which may lead to confusion and medication errors.* *The use of an umbrella segment, unless the portion used is significant and evident when the name is considered as a whole, may however, be accepted the first time it is proposed for an invented name. The NRG will not accept the use of the same segment in a second instance.*" This practice is very common and useful for the consumers and pharmacist who clearly identify medicines from a MAH or medicines within the same therapeutic area (respiratory, digestive, etc), and doesn´t lead to confusion or medical errors. We are unaware of cases of confusion, and they should be documented, in fact consumers and health professionals thank this way to create brands and they perceive them more logical. The construction of brands follows a coherence and the use of a part of the owner's name or a common umbrella segment that stablishes a logic relation between medicines is perfectly understandable.	Not endorsed. The use of a common umbrella segment across a range of products for the purpose of marketing unnecessarily increases the risk of confusion. There is no evidence of the absence of potential safety risks related to the use of umbrella branding; therefore, the EMA takes a cautious approach to the use of umbrella brands for centrally authorised medicinal products. However, the use of same segments within the name of different medicinal products may be accepted on a case-by-case basis provided that there is minimal risk of confusion, and no risk to public health or safety risk associated to their use is identified.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		We have huge experience using the rule of the 3 different letters building new brands to assure enough difference between medicines and we propose to include this possibility. Proposed change (if any): "The inclusion of a common umbrella segment (e.g. part of the name of the sponsor) within the invented names of different medicinal products **should be acceptable if it doesn´t lead to confusion and medication errors. The rule of the 3 different letters can help to differentiate medicines from the same holder (when the segment is part of the name of the sponsor/MAH) or medicines from the same therapeutic area**."	
238 -251 (4.1.12 pronunciation) 238 – 240 249 - 251	1	As to Art. 4.1.12: The first sentence in Sect. 4.1.12 (lines 238 to 239) should remain as it is. The rest of the first paragraph of this section should be deleted. Difficulties in pronunciation that do not involve similarity to other drug names should not be a basis for rejection. That is beyond the legal basis of the NRG under Section 3. It is unclear what is meant by 'prefix'. The same goes for the second paragraph of this section. This paragraph is not appropriate since it is too subjective.	

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		The draft guideline refers to 'repeated vowels or consonants' and not to 'repeated identical vowels or consonants'. For clarification, we suggest to include the word 'identical'. The fact that the EU consists of 27 Member States and 24 official languages makes it evident that very different rules of pronunciation exist. All of them have to be in the same way acceptable. Consequently, also the use of repeated vowels or consonants does not automatically create any additional issues with regard to pronounceability and does also not necessarily increase the risk of confusion with other trademarks already used for the marketing of pharmaceutical products in the EU. Repeated vowels or consonants exist in a number of European languages, for instance, in German, Italian, Spanish and in Portuguese. Furthermore, each language knows many examples of words which are pronounced in the same way but have a different meaning, for instance, • in German, the term "Bank" is used for the following terms "bank" and "bench" in English language the terms "viel" (which can be translated into English among others into "much" or "a lot of") and "er/sie/es fiel" (in English: he/she/it felt) are pronounced in the same way. The identical pronunciation of "viel", "fiel" is also identical with the pronunciation of the English term "to feel". • In Spanish, the letters "b" and "v" have the identical pronunciation.	Change accepted partially; the terminology 'consecutive vowels or consonants' is now used consistently across the paragraph. This section refers to consecutive vowels or consonants, not necessarily identical. However, it is important to note that such proposed invented names will not be rejected automatically; this criterion will be considered on a case-by-case basis.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		Difficulties in pronunciation that do not involve similarity to other drug names should not result in rejection as there is no basis for this type of rejection under the EU Directive. If the NRG keeps this aspect of ease of pronunciation in its Guideline, this should be a watch-out at most and not basis for rejection. If the NRG finds pronounceability of a name challenging, the NRG should tell sponsors which Member States found pronounceability challenging in order to be transparent and to allow sponsors to fully analyze the concern. Proposed change: Add language at the end of the sentence at line 251: "In the event Member State(s) raise concerns about a proposed invented name, the Member State(s) who raised the concern, and the nature of their objection will be shared with for the Sponsor."	Not endorsed; this forms part of EMA's role in ensuring safe and effective use of centrally authorised medicinal products. If considered sufficiently severe to hamper correct identification of the medicinal product, the NRG is of the opinion that the difficulties to pronounce may constitute adequate grounds for rejection; not being able to identify the product name greatly increases the risk of confusion with other names and medication error. This is already common practice; concerned EU/EEA official languages are always listed in the NRG outcome letter when a comment/objection based on the difficulties to pronounce is endorsed by the Group.
238 -251 (4.1.12 pronunciation) 238 – 240 249 - 251	10	**Comment**: The first sentence in Sect. 4.1.12 (lines 238 to 239) should remain as it is. The rest of the first paragraph of this section should be deleted. Difficulties in pronunciation that do not involve similarity to other drug names should not be a basis for rejection. Newly introduced drug names are accompanied by corresponding pronunciation and awareness information upon launch. The use of unique letter string constructs has been in existence for some time and support differentiation against the existing landscape of available drug product names.	
238-251	4	Together with the attributes provided in Appendix 1, the complements to this existing criterion related to the 'human factor'	Change accepted and implemented; the EMA name similarity analysis process is now

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
(4.1.12 pronunciation)		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: 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.	described under a new dedicated section (see section 6.2).
238-251 (4.1.12 pronunciation)	5	**Comment:** INTA believes that the requirement to consider phonetic characteristics in all EU official languages is too burdensome for pharmaceutical brand development. Although this is a marketing consideration for company trademark development teams, it should not be a steadfast rule or prohibition within the Guideline. The rule against repeated consonants or vowels would not be applicable in all therapeutic areas and is thus too limiting. Moreover, as drafted, the rule is too vague without any specific guidance on what applicants should be considering prior to submission. Finally, it is not clear how difficulties in pronunciation raise an issue of confusion between names of medicines. Prescriptions will be written/documented by health care professionals, so the fact that the invented name may be pronounced differently in different EU official languages should not	Change accepted partially; this section has been further simplified and clarified. However, it should be noted that the main role of the NRG is to consider whether proposed (invented) names could create a public health concern or potential safety risk. It is not restricted to name similarity analysis only. Therefore, if considered sufficiently severe to hamper correct identification of the medicinal product, the NRG is of the opinion that the difficulties to pronounce may constitute adequate grounds for rejection.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		impact the handling and processing of such prescriptions. Pronunciation will not impact readability of an invented name. **Proposed Change (if Any):** Delete or provide clear specific guidance on what applicants should be considering prior to submission in order to satisfy this proposed amendment.	
238 – 251 (4.1.12 pronunciation)	8	Comment: We are not aware of any evidence that difficulty to pronounce/read a name is linked to medication errors. Break-down consonants, repeated vowels/consonants have historically been used in brand names of medicinal products with no medication errors reported, even in countries that have more elaborate systems in reporting name-related errors. While we acknowledge that a difficulty to pronounce/read a name could in certain cases be problematic, this is unlikely to happen with medicinal products that follow typical prescription and dispensing protocols (e.g., oncology/diabetic products that will be prescribed formally to follow proper reimbursement, etc.). We would, therefore, request that the NRG consider limiting such objections to cases where medicinal products are being used in emergency rooms or are likely to be instructed verbally (e.g., during surgery).	Not endorsed. In case of objection raised based on the difficulties to pronounce, the setting of use is given due consideration.
252 – 274 (4.1.13 qualifiers & abbreviations) 252	1	**As to Art. 4.1.13** (partly former Art. 4.1.5) We wonder whether the new second sentence in first paragraph of At. 4.1.13 (line 253/254) does already constitute common practice. There is a similar sentence in the current guideline (Art. 4.1.5, second paragraph, last sentence) where it is written that applicant	Proposed changes accepted partially. In order to facilitate review and potential acceptance of the inclusion of the qualifier, applicants are now required to provide an explanation in all cases.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		may consider providing the NRG with explanations… now it seems to become a requirement. Is this necessary? The second sentence of the first paragraph should be completed by '… on the inclusion of the qualifier / abbreviations." to be consistent with the first sentence.	Change accepted and implemented.
255		Instead of 'refraining from' using symbols etc., applicants should 'carefully consider' using symbols etc. and provide an explanation. 'To refrain from' is too restrictive. Proposed change : Applicants, however, should carefully consider using symbols …"	Proposed change not accepted; these elements are not accepted as qualifiers.
262		We are wondering whether the requirement that names and qualifiers should always be separated by a space is acceptable by all countries. For example, in France this is not allowed.	
271 - 272		The addition in line 271 - 272 to the guideline is welcome and should be beneficial to European HCPs and patients. Further examples of where such an approach may be appropriate would be welcome, e.g. for terms such as pediatric, oral, inhaler etc.	Not endorsed; this was agreed under exceptional circumstances in the context of the COVID-19 pandemic. According to Article 6 of Regulation (EC) No 726/2004, each application for the authorisation of a medicinal product shall include the use of a single name not requiring translations.
273 - 274		The third bullet point (lines 273 / 274) requires clarification. Why should complex names be a risk?	Not endorsed; the length and two separate parts are making the name more complex to identify.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		We fail to understand what is meant by 'complex' names and why complexity of an invented name would pose a risk for patient safety. The word 'complex' should be further defined. This section 4.1.13 addresses qualifiers/abbreviations, so line 273 should likewise be limited. Proposed change (if any): On line 273 after "complex" add "invented names and qualifiers".	Not endorsed; by definition, the invented name is composed of the root name and the qualifier in this case.
252-274 (4.1.13 qualifiers & abbreviations)	4	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	Change not accepted. Additional guidance on the use of qualifiers/abbreviations has been introduced in this revision; the assessment and acceptability of qualifiers has also been further detailed. However, the NRG doesn't wish to adopt a restricted list; it is up to the applicant to propose a qualifier for the consideration of the NRG. In 2009, following the submission of a list of qualifiers by EFPIA, the possibility of having a list of acceptable qualifiers was explored by the NRG, but there was no consensus across the EU. This was further discussed with NRG Interested Parties in March 2014, but it was concluded that most qualifiers accepted by the NRG are product-specific terms proposed by the applicants which cannot be included in a list of recommended qualifiers. Therefore, the NRG is not in a position to establish and recommend the use of standard qualifiers.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
262 (4.1.13 qualifiers & abbreviations)	2	Comment: We suggest a space is not always essential – it depends on the importance of the qualifier and the pack design Proposed change (if any): /	Not endorsed; without a space, the addition of a qualifier would create a different invented name.
267 – 268 (4.1.13 qualifiers & abbreviations)	8	Comment: Provide further clarification regarding the use of a modifier as a means to provide for further differentiation, as well as its relevance in view of NRG's position on the risks associated to omission of qualifiers in clinical practice.	Not endorsed; it is the responsibility of applicants to provide comprehensive justification on the inclusion of the proposed qualifier.
274 (4.1.13 qualifiers & abbreviations)	1	Comment: Requiring the identification of a medical product "unambiguously" is vague as to meaning and subjective in interpretation, and unrelated to the NRG's purpose of ensuring that the invented name is not liable to confusion with the common name, or a common or scientific name accompanied by a trademark or the name of the marketing authorization holder. Proposed change (if any): Delete: "…identify unambiguously…" and insert after "…ability to…" the following: "…ensure that the invented name is not liable to confusion with the common name, or a common or scientific name accompanied by a trademark or the name of the marketing authorization holder."	Change not accepted. The main role of the NRG is to consider whether proposed (invented) names could create a public health concern or potential safety risk. It is not restricted to name similarity analysis only.
275 – 283 (4.1.14 inclusion of device name)	1	Comment: These paragraphs require clarification and should be supplemented with some examples.	Change not accepted. That is already the case, for instance, for inhalers.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		This section also mentions "an (invented) name of a medicinal product accompanied by a device name." Proposed change (if any): The Guideline should explicitly state whether NRG would permit such a combination name when other uses of the device name exist (e.g., ATONET PENJECT proposed as compared to LUMBURU PENJECT).	
275-283 (4.1.14 inclusion of device name)	4	The joint use of the brand names of the medicinal product and the associated devices can lead to confusion that is detrimental to patients (*). • 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.	Change not accepted. The inclusion of such statement would result in a lengthy name which may compromise readability and proper identification of the product. It is also not the purpose of the product name to provide such additional information.
275 – 283 (4.1.14 inclusion of device name)	8	Comment: we consider this amendment very helpful for differentiating between different formulations when a new medical device is introduced. We would propose that such 'unofficial modifiers' be allowed not only for medical devices, but also in cases of different formulations intended for different route of administration.	Change not accepted. In accordance with Directive 2001/83/EC, the name of the medicinal product includes the (invented) name, the strength and the pharmaceutical form. It is, therefore, out of the scope of the product name to provide such additional information. The route

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		For example: 'BrandA 150mg powder for concentrate for solution for infusion' is an intravenous medicinal product. A new subcutaneous formulation is introduced both in a pre-filled syringe AND in a glass vial. It would help the differentiation of the IV versus SC formulations if an unofficial modifier were introduced after the strength, that would aid in selecting the appropriate medication: 'BrandA 600mg MODIFIER* solution for injection' *in addition to any references to the route of administration that may be allowed within section 1 of the SmPC.	of administration will be readily available on the packaging, and in close proximity with the name, strength and pharmaceutical form.
284 – 285 (4.1.15 offensive connotations)	1	Comment: An "offensive" or 'an inappropriate connotation' should not be the sole basis for rejection of a name, because this is not objective. Furthermore, it does not support the EMA's objective of patient safety, nor the NRG's role of preventing confusion between the proposed invented name of a proposed medicinal product and the common name, or a common or scientific name accompanied by a trademark of a marketed medicinal product or the name of the marketing authorization holder. The NRG could perhaps provide its views to the Applicant about these topics but only on an FYI basis in the review outcome. Proposed change (if any):	Change not accepted. The deletion of this criterion may leave the door open for not marketing the product in the Member State(s) concerned by the offensive/inappropriate connotation, which would jeopardise equitable access to medicines for all patients across the EU/EEA. Also, it is worth noting that, at the time of the 2004 review of the NRG guideline, when this section was introduced, EFPIA commented the following:

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		To delete this criterium. Insert: If a Member Country finds the (invented) name of a medicinal product to be offensive or finds it to have an inappropriate connotation in their language, an observation (not a rejection) to this effect may be provided to the Applicant with identification of the nature of the observation and the Member Country making the observation.	*"We agree that the "invented name" should not be offensive in any official language. In view of the many languages in use in the EU, an offensive meaning in one language should be a sufficient reason to allow for more than a single trade mark per application."*
284 – 285 (4.1.15 offensive connotations)	10	**Comment**: An "offensive" or 'an inappropriate connotation' should not be the sole basis for rejection of a name, because this is not objective. Furthermore, it does not support the EMA's objective of patient safety, nor the NRG's role of preventing confusion between the proposed invented name of a proposed medicinal product and the common name, or a common or scientific name accompanied by a trademark of a marketed medicinal product or the name of the marketing authorization holder. Most sponsors will generally perform language studies for their proposed invented names and will have already carefully weighed any potential inappropriate linguistic connotations or translations. The responsibility of screening for and acting upon any potentially offensive connotations that are identified should be on the sponsor, and the presence of potentially offensive connotations should not be the basis for the NRG's rejection of a name. Should an offensive or negative connotation be identified during the course of the review, the NRG could notify the sponsor for informational purposes with regard to the observation and the Member States impacted.	Change not accepted. See previous response. We have examples of proposed invented names which have been poorly linguistically researched in some EU/EEA official languages.
284-285 (4.1.15 offensive connotations)	5	**Comment:** INTA believes there is no legal or factual nexus between the wholly subjective assessments of "offensive" and	Change not accepted. See previous responses.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		inappropriate" and the decision of whether a proposed invented name is not liable to confusion with the name of another medicinal product. As such, INTA believes that the assessment of whether a product name is offensive or inappropriate is not within NRG authority. Within the European Union, the assessment of whether a name is offensive or inappropriate is a matter of Intellectual Property law. Art. 7.1(f) of the European Union trademark Regulation (EU2017/1001) listing the absolute grounds of refusal of an applied for European Union trademark states that "The following shall not be registered […] trademarks which are contrary to public policy or to accepted principles of morality". The European Court of Justice has laid down several principles as regards the criteria to be applied in assessing a trademark under this ground. Thus, the competent authority for the evaluation of a product's (invented) name under those perspectives, which is in addition unrelated with the risk of confusion, are the bodies in charge of the intellectual property. It is evident that this section would be also in contrast with lines 99-100 "The EMA will not take into consideration aspects of intellectual property rights/trademark registration within its review for the acceptability of a proposed (invented) name." **Proposed change (if any):** Delete section 4.1.15.	Also, it is worth noting that, at the time of the 2004 review of the NRG guideline, when this section was introduced, INTA commented the following: *"**INTA agrees with this** but urges that this should be a strong justification for allowing exceptions to the single trademark requirement. As previously stated, the present membership of twenty-five countries and numerous languages in the EU, requires increased flexibility in the enforcement of the single trademark requirement."* It is a well-recognised principle in life sciences practice that regulatory authorities and intellectual property authorities conducts separate evaluations under different criteria, and may come to different conclusions. Past attempts to harmonise the respective views and methodologies further did not bring to any tangible results. EMA pursues the protection of public health and any IP-related considerations are extraneous to its decision-making process. Likewise, the CJEU case-law quoted in the comment (without specific references though) is unlikely to be applicable to the health-driven evaluations made by the NRG, also in light of consistent practices amongst Member States.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
284 – 285 (4.1.15 offensive connotations)	8	Comment: 'EU languages' does not cover Norwegian and Icelandic. Proposed change (if any): …in any of the official EU/EEA languages.	Change accepted and implemented.
288 – 306 (4.1.17 labelling & pack design) 290 – 291 296 - 298	1	**As to Art. 4.1.17** For clarity purposes : add "… may play a role (positive or negative) in the final decision … With regard to the third bullet point (lines 296 – 298), could the NRG provide guidance on the required size of letters in relation to a specific packaging size? Comment: Add a reference to the Guideline on Readability of Labelling and Package Leaflet. The third bullet point (lines 300/301) seems to be already common practice.	Not endorsed. Reference to the Guideline on the readability of the labelling and package leaflet of medicinal products for human use is already made in the last paragraph. This revision also aims to formalise current practices which were not reflected in the guideline so far. Guidance on the required size of letters is out of the scope of this guideline; this is part of the mock-up review and considered on a case-by-case basis as it depends on the actual packaging size.
288-306 (4.1.17 labelling & pack design)	4	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.	Not endorsed. The 'INN+MAH' structure is not the 'first option', but one of the two options foreseen by the legislation. The NRG is not establishing here the basis for systematic rejection of long proposed (invented) names, but encourages applicants to consider space limitations of their packaging when creating (invented) names in order to prevent use of avoidable requests for omission of particulars in the labelling during the MAA procedure. This

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		Proposed change: The size of the packaging should be adapted to the name of the medicine product, at least the INN.	contributes to a **sustainable and integrated labelling strategy**. In essence, the proposed (invented) name should be adapted to suit the pack size.
296-299 (4.1.17 labelling & pack design)	5	**Comment:** As the third bullet of section 4.1.17 is drafted, INTA believes it allows NRG to reject proposed brand names if they are "too long to be accommodated on very small containers". First, the appearance of the product label is not within the purview of the NRG. To the extent the NRG does have authority "Too long" and "very small" are very subjective standards. NRG has provided no guidance on what brand names "lengths" will satisfy these vague standards, or the size of containers that would be deemed "very small." Further, NRG asserts that the (already-approved) brand names will be re-assessed at the time of the review of mock-ups (lines 302-303). If, hypothetically, an already-approved brand name is rejected at the "mock-up stage," and new names have to be submitted, this could jeopardize the final approval of the name, and hence, the medicine, to the detriment of patients. Proposed change (if any): Delete the proposed third bullet at section 4.1.17 (lines 296-299) or provide clear guidance.	Not endorsed. The appearance of the product label is under the remit of the EMA (see article 61(1) of Directive 2001/83/EC); the (invented) name constitutes one of the elements of the labelling. It is in the best interest of applicants to give due consideration to the labelling and pack design and adopt a **sustainable and integrated labelling strategy** at early stage. Accepted (invented) names are not re-assessed at the time of the mock-up review. However, their inclusion on the packaging should not negatively affect the readability of the other critical elements (i.e. INN, strength, pharmaceutical form). The creation of an (invented) name which doesn't suit the size of the packaging would equally overload the latest stages of the MAA procedure.
307 – 310 (4.1.18 approval in other regions)	1	Comment: Since different countries have different patient populations, different disease distributions and different authorisation criteria, we do not think that this requirement is valid. There are many	Proposed deletion not accepted. The NRG received complaints regarding discrepancies of the product profiles between products approved in different regions with the same invented

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		examples of a compound having different approved indications in different territories. This is also beyond the legal basis of the NRG (see lines 131-133) and could be subject to challenge. Proposed change (if any): We propose to delete this paragraph.	name. This entails risks of confusion, off-label use, and non-adherence to the product which should be taken into account by applicants in their naming strategy in case of global branding.
307-310 (4.1.18 approval in other regions)	4	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	
308 (4.1.18 approval in other regions)	11	Comment: The approval of the name outside the EU/EEA is out of scope of this guideline. The user of the medicine would not be able to purchase the medicine from another region and in any case should read the leaflet before using the medicine. **Proposed comment**: remove the requirement	
311- 377 (4.2 INN similarity)	1	Comment: This concerns use of portions of an INN name in an invented name. Avoiding the use of an INN stem in the stem position is reasonable because other drugs may have the same stem. Avoiding the use of part of an INN for a different substance than is contained in the medicinal product is also reasonable. However, there is no safety issue, in similarities between an invented name for a medicinal	Not endorsed. Objections to proposed invented names due to similarity with their own INNs are grounded on the WHO World Health Assembly resolution (WHA46.19) on protection of INNs/INN stems to prevent any potential risk of confusion between invented names and common names.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		product and the INN name for that product's active ingredient. Such names actually increase safety by communicating that the medicinal product contains the active ingredient. Proposed change (if any): Suggest NRG discontinues objecting to an invented name's use of part of an INN name other than the stem in the stem position.	
313-314 (4.2 INN similarity)	4	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 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.	Not endorsed. This section is dedicated to objections based on similarity between proposed invented names and INNs/INN stems.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
313 – 334 (4.2 INN similarity)	8	Comment: Provide further details on the reasoning with respect to similarity with own INN versus different INNs in two separate subsections, in particular in view of the many letter combinations that fail the rule but are routinely accepted. For example: How does the position of the common string of letters impact NRG's interpretation of the 50% rule? Is there more flexibility when less than 50% of the own or different INN is used, even if this constitutes equal/above 50% of the invented name? Are there any additional safety considerations with similarities to different marketed INNs that may impact on the interpretation of the rule? Is there any flexibility with similarities to old INNs not clinically developed?	Comment accepted and implemented; location of the shared letter string within the name is considered by the NRG in the decision-making. Other mitigating factors (e.g. old INN never developed/marketed) are taken into account on a case-by-case basis. However, it is important to note that similarity of a proposed invented name with the INN it contains is equally unacceptable to similarity with another INN, as the overall objective is the protection of INNs.
321 – 326 (4.2 INN similarity) 324 - 325	1	**As to Art. 4.2, third paragraph:** This is probably already common NRG practice. Would the 50% similarity rule not be too static? The sentence in line 324 - 325 is overreaching and should be deleted.	1. Comment accepted and implemented; location of the shared letter string within the name is considered by the NRG in the decision-making. 2. Not endorsed: the 50% rule is used as a first-line objective criterion to determine the level of similarity between a given invented name and an INN. Then, other criteria such as the length of

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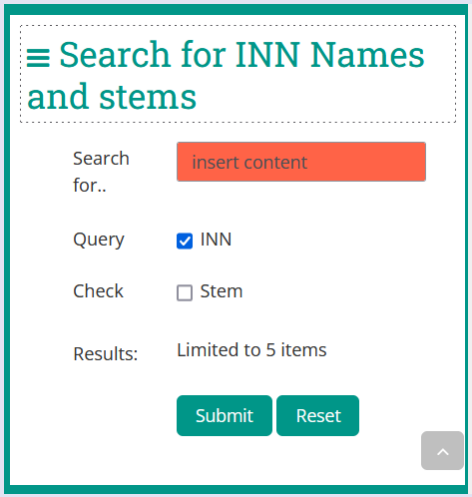
		Two-letter stems do not create issues of confusion or otherwise. For example, -AC is an INN stem and yet several medicines include those letters without association with INN stems (such as Prozac and Zantac). A bar to use of them does create challenges in terms of reducing available letter combinations. The FDA and Health Canada have both dropped two-letter stems as a concern. Reference to checking a proposed invented name as to whether it contains an INN stem should be limited to use of that INN stem in the stem position. For example, INN stems include three letter combinations such as "-ase", "-ast" and "-bep". Those three letter combinations should be available for use in other positions in a proposed invented name. Proposed change (if any): 1. At Line 325 after "…trait" insert "in the stem position." 2. At Line 325 just before "On the basis…" insert the following sentence: "The Group does allow two-letter stems to be used."	the common letter string and its location are reviewed. Precedents are also taken into consideration in the decision-making; therefore, short INN stems may not necessarily lead to rejection.
321-326 (4.2 INN similarity)	4	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:	This WHO Mednet Search tool is already used by the EMA to screen common letter strings and detect similarities with existing INNs. The 50% rule is then applied as an objective criterion to set a minimum threshold to detect a certain degree of similarity between a given invented name and the identified INN.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		 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/	
321-326 (4.2 INN similarity)	9	Comment: "When reviewing INN similarity, the NRG makes use of a 50% similarity rule to support its decision making, with the aim of identifying cases where 50% or more of the proposed invented name is made up of INN parts, and/or 50% or more of the INN is included in the proposed invented name."	Not endorsed. The 50% rule is used as a first-line objective criterion to determine the level of similarity between a given invented name and an INN. Then, other criteria such as the length of the common letter string and its location are reviewed. Precedents are also taken into

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		It is usual for the name of a drug to contain 50% of the fraction of the active substance (especially in those that are better known eg. ibuprofen) and this has not ever been a problem. It is very restrictive to limit it to 50 %. Proposed change (if any): It should be changed in line with what the community code (Directive 2001/83) specifies: not to be confused with the DCI, without specifying percentages: 20. Name of the medicinal product: The name, which may be either an invented name **not liable to confusion with the common name**	consideration in the decision-making; e.g., short INN stems may not necessarily lead to rejection.
323 (4.2 INN similarity)	1	Comment: In its discussion about containing INN parts "parts" is overbroad and could lead to consideration of any letter similarity as being objectionable. Furthermore, if the proposed invented name contains 50% or more of INN parts, it must be a contiguous part or string of letters that comprise the 50% or more. Proposed change (if any): Edit the language to make clear that "parts" means string of letters and not individual letters. Insert after "…INN parts…" on line 323 the following: "where a part consists of a continuous letter string making up the 50% or more of the same letter string in the proposed invented name,…" AND after "…or more…" also on line 323 insert: "…of a continuous letter string…"	Not endorsed. The 50% rule refers to all the letters and is not restricted to common letter strings only. It is used as a first-line objective criterion to determine the level of similarity between a given invented name and an INN. Sequence of letters, common letter strings and their location are taken into consideration at a later stage in the decision-making.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
327 (4.2 INN similarity)	1	Comment: When reviewing similarity to INN, phonetic similarities such as Y and I may also play a role in the decision of the NRG, see Appendix 1 for further examples." should be moderated to avoid the prejudicial presumption that letters are considered interchangeable.	This statement only applies to letters pronounced in the same way, e.g. 'y' and 'i', or 'c', 'k' and 'q'. Although not considered in the 50% rule counting, such phonetic aspects may strengthen similarity between a given invented name and an INN, which may increase the risk of confusion.
335-372 (4.2. INN+MAH names)	4	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, 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.	Considering that former section 4.3.6 was not related to product-specific concerns *per se* (such as vaccines, radiopharmaceuticals, etc.), information has been reshuffled to include all general considerations related to INN under a single section for ease of reference.
346 (4.2 order of active substances in generics)	2	Comment: May EMA specify the rules for including salification in the name Proposed change (if any): /	This information is already reflected in the following bullet: '*In the case of established active substances where the strength has traditionally been expressed on the basis of an unpublished INNM instead of the WHO recommended INN, the unpublished INNM shall be used if the*

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
			applicant/MAH can justify the extensive and well-known use of the INNM versus the recommended INN.'
351-354 (4.2 modified INN)	4	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	The strength can also be expressed in terms of salt if such traditional expression of strength can be demonstrated. See Guideline on Summary of Product Characteristics (SmPC): *'In the case of established active substances in medicinal products where the strength has traditionally been expressed in the form of a salt or hydrate, the quantitative composition may be declared in terms of the salt or hydrate, e.g. '60 mg diltiazem hydrochloride'.'*
373-377 (4.2 lengthy INN+MAH names)	4	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 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.	Not endorsed. This paragraph is not an exclusion criterion but aims to raise awareness on this concern flagged by HCPs for the consideration of the applicant in their naming strategy. See response to similar comment on section 4.1.17.

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416-417 (4.3.4 non-prescription products)	11	Comment: The reference to 4.3.9 should be changed to 4.3.7 as there is no section 4.3.9 The use of "umbrella branding" is a common practice in self-care industry. The importance and value of brand is recognised across Europe; aiming at encouraging and rewarding investment, legislation provides manufacturers with the possibility to apply for trademarks to protect their brands. The holder of a trademark has a strong interest in preserving the goodwill adhering to a brand and, consequently, maintaining a high level of quality for products bearing this brand name. A brand supports identification and differentiation of the product by patients and pharmacists. The use of prefixes, suffixes or qualifiers can clearly indicate the target group or target indication for which products are meant without causing any confusion. The package livery also helps characterising the product and its use (indication, target population). Companies routinely perform a risk assessment for the new candidate name evaluating a number of parameters (APIs, indication/therapeutic class, target group, route of administration, dosage form, treatment duration, contra-indications, warnings and precautions, interactions, overdose, etc) and analysing the likelihood and impact of confusion between the candidate name with an already existing brand product. Based on the rating from the likelihood and risk analysis, a final 'score' is deduced which it	Comment accepted and implemented. Not endorsed; this provision is applicable regardless of the legal status and conditions for supply.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		taken into account in the decision making as to whether the candidate name can be retained or not. **Proposed change (if any):** In view of the above considerations, the specific **restrictive** criteria as described under section **4.1.5, 4.1.11**, 4.1.13 and **4.3.7** may not apply here.	
417 (4.3.4 non-prescription products)	9	Comment: It seems to be a mistake: 4.3.9 doesn´t exist, it should be referred to 4.3.7 Proposed change (if any): In view of the above considerations, the specific criteria as described under sections 4.1.13 and **4.3.7** may not apply here.	Comment accepted and implemented.
418 – 419 (4.3.4 non-prescription products)	1	These lines should be read together with lines 214 – 222 (Art. 4.1.8). the main difference is that they should not have a "positive connotation" anymore but should only be "informative without being promotional". We wonder whether this is not too strict. In principle, a name could have positive connotations without being promotional. Proposed change (if any): On line 419, just after "…without being promotional" insert: "(see section 4.1.8)."	Change accepted and implemented.
430 – 433 (4.3.5 generic/hybrid/similar biological medicinal products)	2	Comment: Examples should be provided. Should different names be used? When should there be "special consideration"? For a new MA Application? When the hybrid procedure is used to add a line extension, is it possible to differentiate?	Without prejudice to the application of Article 1(20) of Directive 2001/83/EC, the WHO Guidelines invite applicants to consider using invented names for biosimilar medicinal products.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		Proposed change (if any): /	In case of line extension, the single name principle laid down in the article 6(1) of Regulation 726/2004 prevails.
434 – 437 (4.3.5 generic/hybrid/similar biological medicinal products)	1	Comment: this requirement should be further clarified.	This is not a requirement *per se* but an additional element for the consideration of the applicant.
434-437 (4.3.5 generic/hybrid/similar biological medicinal products)	4	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	As stated in the first part of the sentence, this element is without prejudice of application of Article 1(20) of Directive 2001/83/EC.
434 – 437 (4.3.5 generic/hybrid/similar biological medicinal products)	8	Comment: Unclear format of current text in brackets. … unique brand **(i.e. invented) name.** Proposed change (if any): … biosimilar medicinal products should be clearly identifiable by a unique brand name.	Change accepted and implemented.
444 – 445 (4.3.7 combination products)	1	Comment: The sentence "...it is not acceptable to insert the whole invented name of the individual active substance(s) in the proposed invented name for the fixed combination" is contrary to long-established precedent in the industry which is useful and communicative for patients and HCPs by clearly indicating that a	Not endorsed. A cross-reference to section 4.1.5 has been included for ease of readability.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		new medicine is a combination of an existing product with an additional ingredient. For example, Actelsar and Actelsar HCT, Micardis and MicardisPlus are more likely to be helpful than giving the combination a completely unique name. As long as names are usefully communicative such a construction should be acceptable and these lines represent an unreasonable restriction. Proposed change: to delete lines 444-445, any concerns about misleading combination product names can be addressed under the preceding paragraph.	
446-448 (4.3.8 multiple applications) and related 455-456	1	Comment: Section 4.3.8 speaks of multiple applications and provides an example of "different indications" and Section 5 at lines 455-456 also suggests a separate MAA in the case of a "new indication." There isn't a clear basis for these two separate mentions of a dual name based on new indications, so should be consolidated. In any event, the wording used in respect of orphan applications should be used to set the standard for review rather than vague language such as used at 4.3.8 :"…should not lead to confusion." Proposed change (if any): Consolidate section 4.3.8 and content at lines 455 and 456 then add the standard used for orphan drugs: "When reviewing the acceptability of (invented) names for multiple applications, e.g., for different indications, the NRG applies the same approach as for other medicinal products. It is of particular importance when seeking a dual name for a medicinal product to provide detailed information on the specific setting(s) in which the	Changes not endorsed. Considering that two duplicate/multiple applications may have separate life cycle, this paragraph relates to the risk of confusion in case of different therapeutic indications (target population(s), target condition(s)) for the same active substance, which could lead to a high potential for harm. According to the EMA pre-authorisation guidance, '*Where the applicant submits proposed (invented) names intended to be used in the context of multiple marketing authorisations/applications, it shall specifically request the NRG to consider whether the proposed (invented) names cannot be considered potentially confusing with each other.'*

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		product is to be dispensed and used as well as on the target population(s)."	
447 (4.3.8 multiple applications)	1	Comment: The NRG should share a list of relevant factors it considers important in helping to determine what helps ensure that "…such applications not lead to confusion…" Proposed change (if any): Insert after "…(see section 6.1). "When proposing a further application based on different indications, the Applicant should consider the following relevant factors to help establish that the indications are different [insert list of relevant factors]."	
457 – 460 (5 prodrugs)	1	Comment: Prodrugs generally have a different INN from the parent active substance, and it does not appear appropriate that products with different INNs should share an invented name. We request review of this proposal and examples of the kind of situation in which the NRG would consider this appropriate.	This issue is mainly driven by the assessment. In this case, the single name principle laid down in the article 6(1) of Regulation (EC) No 726/2004 prevails: • if the prodrug is sufficiently similar to qualify for a line extension, the **same** (invented) name should be used; • if the prodrug is too different, a separate MA will be required, which involves a **different** (invented) name.
457-459 (5 prodrugs)	4	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	
460 (5 prodrugs)	11	Comment: we believe 'name' is meant here **Proposed change** (if any): change MA into 'invented name'	Change accepted and implemented.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
465-467 (6 assessment of phonetic and orthographic similarity & appendices)	1	Comment: For a better understanding and to facilitate the respective use of Appendix 1 and Appendix 2, we suggest to add in line 466: `… assessment of phonetic and orthographic similarity with other invented names. **Attributes to take into consideration to determine the degree of similarity between the names are provided in Appendix 1**. Furthermore in order to ensure … the NRG makes use of an assessment checklist **highlighting the products characteristics to consider** to support the review of these similarity-based objections (see Appendix 2)….	Not applicable; the Appendix 1 has been deleted, and relevant examples of attributes have been included throughout the section 6.
465-470 (6 assessment of phonetic and orthographic similarity & appendices)	4	We agree with the importance of the invented name assessment, but the elements required by the assessment 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.	Change accepted and implemented; the EMA name similarity analysis process is now described under a new dedicated section (see section 6.2).

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		Proposed change: Provide a more detailed methodological background to usefully assess the safety of proposed names	
473-477 (6. Art 57)	4	The public raw data from Article 57 database is a basic source, but not easy to manage in order to identify eventual 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	Comment noted for future consideration. The EMA is in the process of developing its own phonetic and orthographic name similarity algorithm.
474 – 475 (6. Art 57	1	For clarity purposes, we suggest to add: …. Before making a submission to the NRG, **Applicants should carefully consider the existing medicinal products authorized in the EEA through the national route or through the EMA centralized procedure. These data are publicly available in the Article 57 database** which holds the following information: …..	Change accepted and implemented.
487-490 (6.1 submission requirements)	4	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	Comment noted for future consideration. The EMA is in the process of developing its own phonetic and orthographic name similarity algorithm.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		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.	
493 (6.1 submission requirements – number of names)	2	Comment: In the context of MRP/DCP procedures up to three names can be proposed. Therefore, we suggest it should be possible to consider up to three names for CP. Proposed change (if any): /	Change not accepted. The 2-name limit was introduced in 2014 (revision 6); this measure helpt improve outcomes and gain efficiency by rationalising the NRG workload without affecting the acceptability rate.
496-506 (6.1 submission requirements – number of names)	1	Comment: Clarification needed, on whether this means a change to current situations where, if there are 2 names accepted (either conditional or not), 1 or 2 additional names can be requested, with the understanding that at the end of the process, only 2 names can be retained? Proposed change (if any): We recommend clarification.	Where two proposed (invented) names have been fully accepted by the NRG for a MAA, new requests under the same application are not allowed. If one or two of the proposed (invented) names has/have been accepted conditionally, the NRG will allow new requests for the review of additional proposed (invented) names only if the applicant commits to withdrawing the conditionally accepted one(s). If the latter

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
			remains their first choice in the priority order, no further submission will be accepted.
503 – 504 (6.1 submission requirements – conditional acceptance)	1	Comment: '*if an applicant wishes to retain a conditionally accepted name together with a fully accepted name, no further submissions will be accepted'* is too strict and should be deleted. The applicant should have the right to opt out of a previously accepted name, since there are many reasons why a name is no longer appropriate for the company. Furthermore, if we understand correctly, in application of the Conditional Acceptability principle as described in Section 6.6, a fully accepted name may become "conditionally accepted" as long as the name is not included in a MAA. For the Applicant this may result in having 2 names conditionally accepted. Proposed change (if any): We propose to delete the sentence.	Change not accepted; considering that a maximum of two proposed (invented) names per MAA can be accepted, this means that any new proposed (invented) name reviewed and accepted by the NRG would be withdrawn subsequently by the applicant willing to prioritise their conditionally accepted name(s). In this case, the assessment of further proposed (invented) name(s) is pointless and constitutes an abusive use of the NRG review and resources in the context of limited capacity of the NRG agenda for each plenary.
503 (6.1 submission requirements – conditional acceptance)	1	Comment: Redundancy of "…fully accepted…" at line 502 and "…provided they have been accepted." At line 503 Proposed change (if any): Delete "…provided that they have been accepted."	Change accepted and implemented.
506 (6.1 submission requirements – global constraints)	1	Comment: We believe that documentary evidence is a new requirement and such documentation may not be available in all instances. The NRG should describe the documents which it would accept. Proposed change (if any): To insert examples of the kind of documentary evidence the NRG would find acceptable.	Change accepted and implemented.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
507 – 511 (6.1 submission requirements – order of preference)	1	Comment: We fail to understand how this limitation in the review of the number of names may save time, since NRG will have to do the preparation work anyways. We therefore propose to delete the paragraph. This section implies that where a sponsor has had one name approved and submits two additional names for review, the NRG meeting will not issue a decision on the 2nd name if the first is acceptable. This would be a major loss of value for both the EMA and the sponsor only to save a small amount of time in the NRG meeting. Please consider that the NRG has already spent weeks doing background work on both names and the relevant information for a decision has been gathered internally and from member states, and the work has been prepared and presented to the NRG. In comparison, only a short time would be required in the NRG meeting to issue a decision on the 2nd name. Furthermore, we consider that review of justification applications should remain separate from the two new names review process. Proposed change (if any): We propose to delete the paragraph.	Change not accepted; by saving time not going through objections raised for proposed (invented) name(s) lower in the order of preference, this new measure allows for expedited reviews, hence additional capacity during a given meeting to assess proposed (invented) names beyond the 75-name limit per agenda. Moreover, the additional time gained by not reviewing the above names is invested in better analysing and assessing the rest of the proposed names in a given plenary meeting.
507 – 511 (6.1 submission requirements – order of preference)	10	**Comment**: This section implies that where a sponsor has had one name approved and submits two additional names for review, the NRG meeting will not issue a decision on the 2nd name if the first is acceptable. This would be a major loss of value for both the EMA and the sponsor. Please consider that the NRG and the Member States have already performed the background assessment on both names. In addition, the relevant information for a decision has been gathered internally and from member states, and the work	

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		has been prepared and presented to the NRG. In comparison, only a short time would be required in the NRG meeting to issue a decision on the 2nd name. Sponsors understand that if both names are considered acceptable, that one must be relinquished. However, the outcome on the relinquished name could still be useful in informing a resubmission or re-use of said invented name. Examples of how both NRG and sponsors suffer under this proposal: • If the 2nd name is unacceptable but the sponsor is **not** advised of this, the sponsor may submit that name again in a later round, obliging the NRG to again do all of the preparatory work and issue a negative decision at a later meeting. This represents opportunity cost to both sponsor (submitting a name with low likelihood of success) and to the NRG (obliged to do the same preparatory work again on a name they have already 'mostly' assessed as unacceptable). • If the 2nd name is acceptable and sponsor **is** advised of this, the sponsor is likely to resubmit that name if necessary in a later round rather than another candidate, leading to a higher likelihood of positive decisions at a later stage (better for both NRG and sponsor) **Proposed change** (if any): We propose to delete the paragraph and to continue the current approach of issuing a decision on both names.	
520 – 521 (6.2 consultation with MS &	1	**As Art. 6.2**	The list of NRG members (i.e. attendees and contact points) is published on the (Invented) Name Review Group page of the EMA website. As

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
medication safety experts) 525 - 527		Comment: The guideline makes a reference to experts in medication safety. Could the NRG clarify who are these experts in medication safety are? Patient/consumer organizations, HCP organizations are somehow new players in the process. It will be interesting to see whether it has an impact on acceptance and/or rejection rates. Proposed change: Add starting on line 527: "Such consultation should be limited to safety arising from confusion and should be evaluated on the basis of best available evidence and research. Each consultant will be subject to confidentiality."	per Mandate, objectives and rules of procedure for the Name Review Group (NRG), NRG experts have proven experience in their field of expertise (i.e. medication error, hospital pharmacy, community pharmacy) and are selected from the European experts list. The specific provisions for handling declaration of interests and confidentiality undertakings as defined in the Policies on the handling of competing interests are applicable to all NRG members and experts participating in the activities of the NRG. It should also be noted that the NRG members, as well as observers and all experts, shall be bound, even after the cessation of their duties, not to disclose any information, which, by its nature, must be covered by individual professional secrecy.
529-53 (6.3 NRG/CHMP discussion/adoption & due diligence Art 57)	4	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.	Comment noted for future consideration. The EMA is in the process of developing its own phonetic and orthographic name similarity algorithm.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		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.	
544 – 545 (6.3 NRG/CHMP discussion/adoption)	1	Comment: There is an open-ended aspect to the statement of "all relevant factors" this should be limited to what is enumerated in the guidance. There is no procedural guidance around "if further clarifications are to be submitted by the company." Proposed change (if any): Amend to state: "After evaluation of the relevant factors outlined in this guidance…" Insert timing and nature of clarifications with examples would be helpful.	Change accepted and implemented.
547 – 551 (6.3 NRG/CHMP discussion/adoption & changes to profile)	8	Comment: We propose to extend the definition of reconfirmation to these cases too (i.e., changes to key aspects of the product profile).	Not endorsed. Reconfirmation of an accepted (invented) name only refers to the extension of the expiry date; changes to key aspects of the product profile would fall under the scope of 'review of names based on new information received by the NRG'.
550 (6.3 NRG/CHMP discussion/adoption & changes to profile)	1	Comment: The NRG asks for notification of changes at the time of the initial MAA or during the evaluation procedure, but does not provide any process guidance about how to effect such a notification. Is a simple e-mail to the NRG mailbox sufficient? How should it be communicated?	Change accepted and implemented.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		Proposed change (if any): Insert process details outlining what content (Revised Name Review Form?), to whom, and how the notice is to be provided.	
552 – 554 (6.3 NRG/CHMP discussion/adoption & acceptance period)	1	Comment: The acceptability of invented names should be considered for a period of 3 years from the time of CHMP adoption, as it previously was. This period of time is more in line with usual development timelines of a product. The period of extension could be limited to 2 years upon request from the applicant. For clarity, this total timeframe should be identified as the "validity period" since it is referred to at other portions of the Guidance. In order to link this section with Section 6.8.2 and Section 6.9.2 a reference to "validity" should be expressed. Proposed change (if any): Validity of accepted invented names : The NRG considers the acceptability of invented names for a period of 3~~2~~ years from the time of CHMP adoption. This period can be extended once for a further 2 years period upon request from the applicant. (see section 6.9.2). At Line 554, after the "…(section 6.9.2)…" insert "…referred to as the "validity period."	Change partially accepted. The NRG agreed to revert to previous initial 3-year validity period. However, based on the low number of requests for reconfirmation submitted since 2014, and in an effort to decrease the number of conditional pairs with back-up names, the NRG decided to limit the period of extension to 1 year upon request from the applicant. Please rest assured that this new provision will not be implemented retroactively; accepted invented names will remain valid in the NRG database until their expiry date.
552 – 554	10	**Comment**: We disagree with the proposal to reduce the initial period of acceptability to 2 years.	

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
(6.3 NRG/CHMP discussion/adoption & acceptance period)		The acceptability of invented names should be considered for a period of 3 years from the time of CHMP adoption, as it previously was. This period of time is more in line with usual development timelines of a product. Therefore, we feel that the original 3-year period should be maintained. We agree, the period of extension could be limited to 2 years upon request from the applicant. For clarity, this total timeframe should be identified as the "validity period" since it is referred to at other portions of the Guidance.	
Lines 552-553 (6.3 NRG/CHMP discussion/adoption & acceptance period) And Line 721	7	The NRG considers the acceptability of invented names for a period of ~~2~~**3** years from the time of CHMP adoption; this period can be extended once for a further ~~2~~**3** years upon request from the applicant (see section 6.9.2). The reconfirmation on an approved (invented) name is the extension of the expiry date by a further ~~two~~ **three**-year period. Comment and rationale: When initially submitting a proprietary name to the EMA (even if this should be done maximum 18 months before MAA), it is not possible to know exactly when the MA will be ready for submission and unexpected delays may occur. This is especially complex for small companies, when the EMA is not the only regulatory agency that the company is filing to and if a different agency is submitted to prior to filing for the MA. Any delays in submitting or receiving final approval of an Invented Name by an alternative regulatory agency can push timelines out by even a couple of years. Using the same proprietary name internationally optimizes patient safety and reduces quality, labelling and packaging system complexities and risks.	

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		For proprietary names submitted 2 years ago, where the MA is not ready for filing because of unexpected delays, if an extension is not performed imminently, the name would expire as soon as version 7 is implemented. If submission of the MA is not performed within 2 years from that date because of unplanned delays, the name would no longer be usable according to 6.2.9. In addition, it may be best to avoid wasting EMA resources by reassessing the proprietary name prior to final acceptance of the name by the first regulatory agency. An adoption and extension period of only 2 years is challenging when managing submissions in multiple markets, with multiple regulatory agencies.	
560 (6.4 Applicant/MAH communication and follow-up & information on MS)	1	Comment: Specificity concerning specific country-based objections which form the basis of the rejection should be clearly communicated. Proposed change (if any): Insert the following after the word "source" and before the word "for" "…including where an objection arises from one or more member Countries identification of those countries and their specific basis.."	Change not accepted; this is already common practice. Concerned EU/EEA official languages are always listed in the NRG outcome letter when a comment/objection based on the difficulties to pronounce is endorsed by the Group. In case of rejection based on similarity with the name of a nationally authorised product, relevant public data are readily available in the Article 57 database.
572-577 (6.4 Applicant/MAH communication and follow-up &	4	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.	Changes not accepted. The NRG considers that the proposal for EMA to encourage the use of INN-based brand names composed of the INN and the name of the company as first option, is not acceptable for the following reasons:

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INN+MAH 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.	• In line with Article 1(20) of Directive 2001/83/EC, whereby the name of the medicinal product "may be either an invented name not liable to confusion with the common name, or a common name or scientific name accompanied by a trade mark or the name of the marketing authorisation holder", the NRG considers invented names and INN +MAH/TM names to be equal in status. • The is no evidence to support that such a change would result in a reduction of medication errors related to naming. • The use of INN+MAH names may have an impact on labelling, e.g. space constraints on small labels. • There may be cases where INN+MAH names are not considered appropriate, and create a divergence with other regions, also vis-à-vis the desire for global trade names. • The encouragement of INN+MAH names as a first option may be at odds with other regional approaches, such as the use of random 4-letter qualifiers in the US for biologicals. The NRG does not consider there is a need to create a different procedure for their review and approval. The NRG, however, will fast-track their

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
			review via written procedure if a CHMP Opinion is imminent, and no name has been obtained by the applicant. A decision to waive the variation fee when pharmaceutical companies decide to replace an invented name with an INN-based name is not within the remit of the NRG or the scope of the revision of this guideline, and would require a revision of Fee Regulation (EC) No 297/95. Lastly, it is within the scope of the mock-ups and specimens review to ensure that the information provided in the packaging is seen in the context of the complete product information and balanced in regards to the overall pack design.
585 – 587 (6.5 rejections & information on MS)	1	Comment: We appreciate the mention of individual Member countries. Following our suggestion at Line 560, further clarification about which countries have raised objections should be included. Proposed change (if any): Insert at the end of the sentence at line 587: "In case of rejection based on Member state(s) objection(s), the Member country(ies) and specific objection(s) in each case will be shared with the Sponsor.	Change not accepted; this is already common practice. Concerned EU/EEA official languages are always listed in the NRG outcome letter when a comment/objection based on the difficulties to pronounce is endorsed by the Group. In case of rejection based on similarity with the name of a nationally authorised product, relevant public data are readily available in the Article 57 database.
585-587 (6.5 rejections & information on MS)	4	Seems to be duplicated in lines 593-595 Proposed change: To remove one of these occurrences.	Comment accepted and implemented.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
615-646 (6.6 conditional acceptance & bilateral negotiations)	4	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 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.	Not endorsed. The EMA doesn't interfere but solely facilitate initial communication between the two parties if they both confirm their interest. The EMA is not involved further in the negotiation process. Aspects related to intellectual property rights and trademark registration are not considered by the NRG while reviewing the acceptability of a proposed (invented) name.
616 – 620 (6.6 conditional acceptance & bilateral negotiations)	1	Comment: Could EMA provide more clarity about the terms "with a MA in place", "Ongoing MAA … MA pre-submission phase": are these steps considered to fall under "pending submissions"?	Change accepted and implemented. The guideline refers here to a valid MA as opposed to a medicinal product at pre-submission stage or whose MAA is ongoing. The term 'pending submission' includes pre-submission phase and also ongoing MAA. A clarification note has been included in brackets.
616-646 (6.6 conditional acceptance & bilateral negotiations)	6	Comment: There is a new section in the draft guide introducing the **conditional acceptability and bilateral negotiations between the concerned applicants** (6.6). The procedure is not clear, it can be problematic and if implemented, it might lead to delays in approvals of MAAs.	Not endorsed. Only the MA gives legal power to claim right on naming. The proposed approach would restrict unreasonably applicant's choice for (invented) name and lead to unjustified rejection. Considering that the contending

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		We find it worrying that proposed names which only have similarity-based objections with the name(s) of a pending submission, but not of authorised products, are considered to be 'conditionally' accepted. While preparing the submission, the applicants need to work with a potential trade name to be able to submit the labelling information and mock-ups at the same time. This might waste valuable resources on the applicant's side, if in the end the proposed name will not be accepted. This might happen very close to the end of the assessment. Line 625: "A MA may be granted with the conditionally accepted name, if a MA for the contending name has not yet been granted." In means that the applicant of pending MAA with an accepted name cannot be certain of being able to use this name if in case another application with a conditionally accepted name similar to the accepted name might gain approval sooner on a faster track. Bilateral negotiations are based on the goodwill of the two parties with conflicting interests, therefore the negotiations might not be arranged easily and therefore both applications could be hindered. With the EMA only being part of the initial step of the process, negotiations between the two parties are not regulated at all. This delay might come in the late stage of assessment and if the two parties cannot meet an agreement within a given amount of time, there might be a delay in launching a product, thus getting a potentially life-saving medication to the patients might be delayed too. This process increases the uncertainties of the assessment process and add further risk to the planning of launch activities. Proposed change (if any):	(invented) name is not granted with marketing authorisation at this time, the risk of confusion is not actual. Lastly, the possibility of bilateral negotiation is not a new concept; the text has been amended to reflect current practices.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		The increase in uncertainties in planning should be avoided, this is the interest of all parties. Therefore, we suggest granting priority and protection to the accepted proposed name of which the marketing authorisation application was submitted first, even if the second application with a conditionally accepted contending name might seem to gain approval sooner. A conditional name should become an accepted name only when the application with the accepted proposed name is withdrawn or refused and the accepted name expires. (This is in line with the current proposal, but please see the comment to 6.8.2 Expiry of the accepted name as well.) If a proposed name is conditionally accepted, the applicant can take the planned risk that this name will not be changed to an accepted name and they have to change to an alternative accepted name. This risk would be known and can be planned by the applicant. We do not support the introduction of bilateral negotiations, as these are not controlled, may be time consuming and increase uncertainty in the procedure.	
619 – 620 (6.6 conditional acceptance & bilateral negotiations)	6	Comment: A question to be clarified: What happens if a proposed name is found to be similar only to a conditionally approved name? How should this proposed name be considered? Proposed change (if any):	This proposed (invented) name would be considered accepted conditionally. Following CHMP adoption of the NRG conclusion, the contact person of the contending (invented) name will be informed of this new objection due to similarity with the invented name proposed for another pending marketing authorisation application.
631 – 633 (6.6 conditional acceptance &	1	Comment: We recognize that the NRG cannot disclose any confidential information, however might it be possible to disclose whether a name of concern is related to an actual Marketing Authorisation Application (as opposed to a pre-MAA procedure)?	Not endorsed. The EMA cannot disclose any information regarding the contending name, including the MAA status. This is considered

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
bilateral negotiations)			commercially confidential information whose disclosure might prejudice the commercial interests of the other applicant to an unreasonable degree.
634 – 641 (6.6 conditional acceptance & bilateral negotiations)	1	Comment: Clarity / transparency requested about the fact that an Applicant Nr 1 who has received a first preliminary approval of its name is informed that its name appears similar to a newly submitted name submitted by Applicant Nr 2 and becomes conditionally approved. Proposed wording: The NRG secretariat is responsible for informing the Applicant of an already accepted name that its name is conflicting with an invented name newly proposed by another Applicant.	Change accepted and implemented. This complies with current practices.
662 (6.7.2 other post-authorisation activities)	1	Comment: Delete "… such adverse …" which is repeated twice. Proposed change (if any) Delete the "such adverse" redundancy.	Change accepted and implemented.
668-675 (6.7.2 other post-authorisation activities)	4	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 a 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.	Comment noted for future consideration.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		Proposed change: 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.	
684 – 685 (6.8.1 withdrawals)	8	Comment: Include further clarification on when a request for withdrawal can be submitted and whether this withdrawal alone would allow for review of additional names at a later stage in the context of the same MAA.	Comment accepted; this section has been amended accordingly.
688-692 (6.8.2 expiry)	1	Comment: We assume this refers to the validity period referred to in lines 552-555. Proposed change (if any): On line 690 after "…even if the…" insert "…validity period…" so that it reads: "…even if the validity period expiry date is reached."	Change accepted and implemented.
688 – 691 (6.8.2 expiry)	6	Comment: If the accepted name becomes automatically withdrawn when the MAA is withdrawn or refused, the applicants have to ask for reassessment of the previously accepted proposed name if the resubmission of the product with the same profile is considered. Proposed change (if any): If the application is withdrawn or refused let the applicant ask for an extension of validity of the acceptable proposed name for another two years. In this case the same name can be used if they intend to submit the application again with extended documentation.	Comment accepted; this section has been amended accordingly. A definition of the 'in use' status has also been included.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
689 – 690 (6.8.2 expiry)	1	Comment : For clarity purposes, a reference to section 6.3 should be added: "… will not expire during the MA procedure, even if the validity of the accepted invented names, as defined in Section 6.3 is reached."	Change accepted and implemented.
695 (6.9 re-use and reconfirmation)	1	Comment: For clarification purposes, we suggest the following modification : "… These criteria do not apply to accepted invented names for which the validity is expired (as defined in Section 6.3)	Change accepted and implemented.
701-718 (6.9.1 re-use)	4	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 descriptive analysis" *BMJ Quality & Safety* 2020; **29** (12):988-991. Proposed change:	Correct. In order to merge all guidance into a single document, the EMA took the opportunity of the 7th revision to integrate the re-use position paper into the NRG guideline. Proposed change not endorsed. The NRG gives due consideration to product awareness and safety issues when reviewing the re-use of (invented) names already used in a marketing authorisation application.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		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.	
702-712 (6.9.1 re-use)	3	Comment: suggest deletion (most of section 6.9.1, which deals with re-use) Proposed change (if any):	Comment not accepted. The re-use concept has demonstrated efficiency gains for all parties, this is why applicants are encouraged to re-use invented names approved as back-up before expiry, taking into consideration the general principles described in this guideline.
713-718 (6.9.1 re-use)	3	Comment: We have seen an increasing number of what we consider to be "well researched" names be rejected due to invented names for products that are 'pending submission.' In an effort to shrink the number of unused ('pending') names that could potentially cause rejections, we propose that the remaining name that is not used as part of the centralised marketing authorisation be withdrawn. Since the appropriateness of any proposed invented name is "strictly related to the product profile," a new safety review would need to be performed to apply the new product profile to the existing name, when such name is transferred to another product's application. The applicant would still be able to submit this name as part of a new MAA in the future. In essence, we propose that the "re-use" procedure be discontinued. Proposed change (if any): 713 According to the current name review process, up to two proposed (invented) names per marketing 714 authorisation application can be accepted by the NRG, out of which only one single (invented) name is 715 to be used as part of the centralised marketing authorisation. The accumulation of a high number of 716	Change not accepted. Proposed (invented) names cannot be rejected solely based on a similarity identified with the name of a 'pending submission'. In such scenario, the proposed (invented) name would be accepted conditionally. The added value of putting in place a system to withdraw back-up names automatically once the MA is issued is questionable since they will reach expiry date anyway.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		accepted invented names which are not used by applicants creates difficulties in finding future 717 acceptable invented names. Therefore, ~~**applicants are encouraged to re-use approved invented names 718 taking into consideration the general principles above.**~~ **following approval of an MAA, an alternative name(s) not selected by the applicant as part of the centralised marketing authorisation will be automatically withdrawn.**	
719 – 721 (6.9.2 reconfirmation)	1	Comment: Title to be reviewed for clarity purposes: 6.9.2 Reconfirmation of **validity of accepted (invented) names** The reconfirmation of an accepted (invented) name is the extension of the expiry date **(as defined in Section 6.3)** by a further two-year period.	Change accepted and implemented.
719-725 (6.9.2 reconfirmation)	11	Comment: We wonder why there is this new requirement given that "once a MAA is submitted the accepted (invented) name is considered to be 'in use' and will not expire during the MA procedure, even if the expiry date is reached." Proposed change (if any):	This is not a new requirement. The text has been amended to reflect current practices.
Line 722 (6.9.2 reconfirmation)	7	Reconfirmation…can be granted only once, before the expiry of the (invented) name. Comment and rationale: If this change from 3 to 2 years comes into effect, the time from a name being reviewed as being 'acceptable' and being available for use, will be a maximum of 4 years. This could invalidate the	General comment noted.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		desired name, even if the name is acceptable. It is possible that companies working with multiple regulatory bodies may be faced with timelines greater than 4 years from initial assessment until MA submission due to unexpected delays.	
752 – 784 (Appendix 1)	1	Based on the goals of increased transparency and predictability of outcomes, we propose to convert the proposed language of Appendix 1 to a checklist format similar to that proposed (and used) in Appendix 2. Please see a draft proposal at the end of this submission document.	The introduction of Appendix 1 was intended to be indicative and highlight aspects of the name construction which could enhance similarity between names. The proposed conversion of Appendix 1 to a checklist is unwieldy and not in line with NRG objectives for its use. Although non-exhaustive, this list was considered as an additional element to take into consideration, in addition to other elements such as POCA, the multilingual check by the Member States (MS), and the differences in healthcare systems across MS, where reaching a harmonised approached may not always be possible. However, it is acknowledged that providing this level of detail without further explanations on how it will be used by the NRG and integrated into the remainder of the process may confuse more than clarify. Therefore, the Appendix 1 has been removed and integrated into the overall explanation of the NRG evaluation process.
754 - 755 (Appendix 1)	1	Comment: Is the degree of similarity of the proposed invented name considered from a global perspective? Please include scope	
773 – 774 (Appendix 1)	1	Comment: This criterium is too vague and lacks clarity on how the guidance is going to be used. Proposed change (if any): The criterium should be deleted	

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
785 (Appendix 2)	1	Comment: The Checklist at Appendix 2 should include all of the relevant aspects as outlined in Section 4.1.1 to help increase transparency and predictability. Proposed change (if any): Add to **Prescription** section in respect of the indication; "Intended patient population"; (added to "prescriber") "Intended health care professional(s)." Add to **Dispensing** Section: "Specialized controls the same or similar?" Add to **Preparation** Section: "Complexity of handling the same or similar?"	Comment accepted and implemented; section 4.1.1 and Appendix 2 have been amended to further align terminology.

PROPOSED INVENTED NAME v. MARKETED NAME

NRG Checklist for Assessment of objections on the basis of name similarities

1. Degree of orthographic and phonetic similarity.

NRG Guidance (Draft Revision No. 7) – Appendix 1 – Additional attributes to assist in determining the degree of similarity

Suggested explanation:

Consider each element of comparison for the proposed name and the marketed name of potential concern and respond YES or NO. Elements 12, 13, 14, 15, 16, and 19 represent PHONETIC elements. Elements 1-9, 11, 16, 17, and 18 represent ORTHOGRAPHIC or "print" elements. There may be instances where the same element in PRINT and WRITING results in different responses. Consequently, the ORTHOGRAPHIC writing element considerations are the same as for PRINT, with the addition of No. 10. The sum of total numbers of YES's and NO's for each category should be captured. A high number of YES's suggests a higher likelihood of confusion, and a high number of NO's suggests a lower likelihood of confusion.

		PROPOSED INVENTED V. NAME	MARKETED NAME
	Element for Comparison	**Phonetic and PRINT Response (YES or NO)**	**Written Response (YES or NO)**
1	Identical prefix		
2	Identical infix		
3	Identical suffix		
4	Similar length of the name		
5	Similar spelling		

6	Upstrokes (capital and lower case e.g. 'P', 'd') in similar locations		
7	Downstrokes (e.g. 'q', 'y') in similar locations		
8	Cross-strokes (e.g. 'x', 't') in similar locations		
9	Dotted letters (e.g. 'i') in similar locations		
10	Ambiguity introduced when scripting letters (e.g., 'P' may appear as 'B', 'D', or 'R'; lower case 'r'; may appear as 'e', 'v' or 'I'; lower case 'a' may appear as any vowel; lower case 'x' may appear as lower case 't', 'f' or 'y' etc.)		
11	Similar number of words/groups of characters in a name (A "word" is considered as any group of characters separated by a space)		
12	Similar number of syllables		
13	Similar stresses (e.g., Trycel and Triafil have similar stresses: TRY-cel and TRIA-fil; try-CEL and tria-FIL)		
14	Placement of vowel sounds is similar (e.g., 'e' may sound like 'a' or 'i'; 'i' may sound like 'a' or 'e'; 'a' may sound like 'e' or 'i' etc.)		
15	Placement of consonant sounds is similar (e.g., 'n' may sound like 'm', 'dn', 'gn', 'kn', 'mn', 'pn'; 't' may sound like 'd', 'b' or 'pt' etc.)		
16	First letter and/or sound (but made with the same letter) is identical		
17	Last letter is identical		

18	Same letters but in different order (e.g., Termix and Trevisc - the "er" and "re" can be interpreted as the same and do not provide protection from name confusion)		
19	Some letters are written but not pronounced (silent letters)		
	"YES" and "NO" Totals Table	YES	NO
	PHONETIC TOTAL (12+13+14+15+16+19)		
	ORTHOGRAPHIC TOTAL ((1-9, + 11 + 16 +17+18) PRINT		
	~~*ORTHOGRAPHIC*~~ TOTAL ((1-11) + 16 +17+18) ~~*HANDWRITING*~~		

The numbers of YES's and NO's for each element should be captured in the "Yes" and "No" Totals Table set out above.

SUMMARY - Degree of orthographic and phonetic similarity

(Adapted from Appendix 2)

To provide a quantifiable basis for selecting "High" "Medium" or "Low" Look-alike, Sound-alike, the total number of YES's and No's for each of the PHONETIC, ORTHOGRAPHIC PRINT, and *ORTHOGRAPHIC Writing* are transferred to the following SUMARY Table. As indicated by the quantitative scale for each, a high number of YES's suggests a higher likelihood of confusion, while a high number of NO's suggests a lower likelihood of confusion with respect to each of Print, Speech and Handwriting.

	HIGH (O= 9-13)		MEDIUM (O=4-8)		LOW (O=0-3)	
PRINT	Y=	N=	Y=	N=	Y=	N=
	HIGH (P=5-6)		MEDIUM (P=3-4)		LOW (P= 0-2)	
SPEECH	Y=	N=	Y=	N=	Y=	N=
	HIGH (O= 10-14)		MEDIUM (O=5-9)		LOW (O=0-4)	
HANDWRITING	Y=	N=	Y=	N=	Y=	N=

Appendix 2 – NRG checklist for assessment of objections on the basis of name similarities

Consider each element of comparison in the tables below for the proposed name and the marketed name of potential concern and respond YES, NO, N/A or Unclear. Count the total number of each and insert in the Row marked "Total" for each Table.

2. Setting of Use, Elements and Potential for Mix-up (Appendix 2)

Possible Risk identified at **PRESCRIPTION** level?	YES	NO	N/A	Unclear
Same therapeutic area/indication				
Same prescriber/intended HCP				
- Close on electronic prescribing lists				
Handwritten prescriptions appear same				
Same intended population				
Emergency situations				
TOTALS:				

The number of YES's, NO's, N/As and Unclear should be captured in the Totals row set out above. Transfer the totals to the Summary Table below.

Appendix 2 – NRG checklist for assessment of objections on the basis of name similarities – Cont'd

Possible risk identified at **DISPENSING** level?	YES	NO	N/A	Unclear
Same storage conditions and proximity (e.g. shelf, fridge, controlled drugs locked cupboard, etc.)				
Close on electronic dispensing lists				
Same dispensing facility (hospital pharmacy, community pharmacy, aseptic department, directly from ward stock, directly shipped by manufacturer on patient named basis, etc.)				
Specialized controls the same				
Emergency situations				
TOTALS:				

The number of YES's, NO's, N/As and Unclear should be captured in the Totals row set out above. Transfer the totals to the Summary Table below.

Appendix 2 – NRG checklist for assessment of objections on the basis of name similarities – Cont'd

Possible risk identified at **PREPARATION** level?	YES	NO	N/A	Unclear
Both to be mixed together prior to administration (e.g. error of dosing)?				
Can they both be put in a Monitored Dosage System (MDS)/Individualized dosing system?				
Complexity of handling the same or similar				
TOTALS:				

The number of YES's, NO's, N/As and Unclear should be captured in the Totals row set out above. Transfer the totals to the Summary Table below.

Appendix 2 – NRG checklist for assessment of objections on the basis of name similarities – Cont'd

Possible risk identified at **ADMINISTRATION** level?	YES	NO	N/A	Unclear
Self-administration in same patient population? (patient may confuse both products at home)				
Both Administered by HCP				
Emergency situations				
TOTALS:				

The number of YES's, NO's, N/As and Unclear should be captured in the Totals row set out above. Transfer the totals to the Summary Table below.

Appendix 2 – NRG checklist for assessment of objections on the basis of name similarities – Cont'd

ELEMENTS that may Increase/reduce the risk of confusion	**SAME** (Insert an X if this applies)	**SIMILAR** (Insert an X if this applies)	**DIFFERENT** (Insert an X if this applies)	**N/A** (Insert an X if this applies)
Strengths				
Pharmaceutical forms				
Route of administration				
Legal Status				
Proposed Labeling				
Totals:				

The numbers of YES's, NO's, and N/As and Unclear should be captured in the Totals row set out above. Transfer the totals to the Summary Table below.

Potential for Harm in case of accidental **mix-up**	High	e.g., death or major injury
	Medium	e.g., minor injury
	Low	e.g., no injury
	N/A	e.g., no risk of confusion identified
	Unknown	e.g., when the actual potential for harm is unknown
	Response:	[Insert response]

There will be only one response for this table – insert it in the lower right cell. Transfer the value to the Summary Table below.

Appendix 2 SUMMARY TABLE – Setting of Use, Elements and Potential for Mix-up

	YES	NO	N/A	SAME	SIMILAR	DIFFERENT	HIGH	MED	LOW	N/A
PRESCRIPTION										
DISPENSING										
PREPARATION										
ADMINISTRATION										
ELEMENTS										
Mix-up										
TOTALS:										

The sum of total numbers of YES's, NO's, and N/A's, "Same" "Similar" and "Different" AND the result from Mix-up should be captured in the above Summary table from each of the above tables.

A high number of NO's *plus* a larger number of "DIFFERENT" versus "SAME" or "SIMILAR" plus a "LOW or N/A for Mix-up suggests a lower likelihood of confusion.

A high number of YES's *plus* a larger number of "SAME" versus "SIMILAR" or "DIFFERENT" plus a "Medium" or "High" for Mix-up suggests a higher likelihood of confusion.