European Medicines Agency
Veterinary Medicines and Inspections

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OVERVIEW OF COMMENTS RECEIVED ON DRAFT GUIDELINE ON THE ACCEPTABILITY OF NAMES FOR VETERINARY MEDICINAL PRODUCTS PROCESSED THROUGH THE CENTRALISED PROCEDURE

Table 1: Organisations that commented on the draft Guideline as released for consultation

Add name followed by link to individual received comment (upon publication by Web Services)

	Name of Organisation or individual	Country
1	IFAH-Europe	Belgium
2	International Trademark Association (INTA)	United States

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GENERAL COMMENTS - OVERVIEW		
IFAH-Europe It is with regret that IFAH-Europe must inform the EMEA that without several key amendments, we consider that this draft revision of the guideline is not helpful. The guideline presents several unnecessary hurdles to industry in finding an acceptable trade name. It does not take into account the fundamental differences in names of products between the human and the veterinary field. Especially with vaccines, there is a considerable veterinary tradition that is distinctively different from human and veterinary pharmaceutical products.		
International Trademark Association (INTA) INTA appreciates the opportunity to provide comments on Revision 3 of the Guideline.		
SPECIFIC COMMENTS ON TEXT		
GUIDELINE SECTION TITLE		
Line no.[1] + paragraph no.	**Comment and Rationale**	**Outcome**
Page 2, Introduction, 2nd paragraph	**INTA** There seems to be no allowance for any "exceptional cases" beyond where the trademark [registration] has been "cancelled, opposed, or [presumably the mark even if not registered] objected to under trademark law in a Member State." Seems like this should be rewritten as "in exceptional cases, *such as* where the proposed trademark has been cancelled, opposed or objected to . . ." Adding "such as" would open the door to potential other "exceptional cases," whatever they may be. For example, what if national health authorities (or other regulators) object to a mark on other than trademark law grounds? Also consider rewording to make it clear that "cancellation and opposition" applies to registrations and applications, whereas "objected to" can presumably apply to registered or unregistered marks.	"However, in exceptional cases, ***such as***, where the proposed trade mark…." Not accepted. Legislation is precise and the exceptional cases are only applicable to trade mark law.

[1] Where applicable

Page 2, Introduction, 4th paragraph	**INTA** The use of standard accepted terminology is recommended when referring to a trademark. This paragraph as well as the Guideline uses the terms brand name, invented name, common name, scientific name, trademark, name of the marketing authorization holder and international non-proprietary name (INN), without any definition of these terms. Invented name appears to be used in the document to mean "trademark" and we recommend that "trademark" be used rather than "invented name."	A definition of trademark is now included in the guideline. The term brand name is not used in the guideline.
Page 2, Introduction, 6th paragraph	**INTA** Although it is agreed that trademark registration is not a function of the EMEA, it is necessary to give weight to the trademark process. Prior to filing for trademark registration, trademark professionals do extensive and thorough searching of prior trademark registrations and applications as well as trademarks in use to ensure that these new trademarks will not be confused with existing trademarks. Once applications are filed at either national or regional trademark offices, these trademarks are subjected to additional searching and examination by a Trademark Examiner and the publication of pending applications for opposition by third parties, including competitors. Therefore, trademarks that have been through the registration process are unlikely to result in medication errors and thus, registration status of trademarks be taken into account as part of the EMEA review.	The CVMP considers whether the invented name proposed for a veterinary medicinal product could create an animal health concern or potential safety risk independently from whether the proposed name is trade marked or not.
Page 3, Section 2.1.1 1st paragraph	**INTA** The guidelines state that *"the invented name of a medicinal product should not be liable to cause confusion in print, handwriting or speech with the invented name of an existing medicinal product (either a veterinary medicinal product or one for human use)."* Veterinary and human medicinal products generally travel through different trade channels and to different consumer groups. There would be very few, if any instances where human and veterinary products would be dispensed by the same personnel or in the same setting and administered in the same environment. Therefore, names for veterinary products should not be rejected on the basis of a name for a human product, except in those rare circumstances, where the names were identical or almost identical, the products are likely to be	This point can be accepted particularly as there is no reference in the equivalent human guideline or cross reference to a veterinary medicinal product.

	either distributed or dispensed through the same channels and it is believed that confusion is likely after consideration of all aspects listed in Section 2.1.1.	
2.1.1	**IFAH-Europe** The invented name should not be liable to cause confusion. When assessing the potential for such confusion, the following aspects of concern were added: indication; animal population; strength; potential harm to the animal in case of a mix up. These are criteria to be used by CVMP in reviewing the acceptability of the name proposed by applicant. The added aspects come straight from the human CHMP guideline rev. 5 by changing the word "patient" into the word "animal". Without defining "animal population" the implications of these criteria cannot be foreseen. This is a not acceptable to IFAH-Europe.	EMEA should give examples on how the "animal population" is considered for evaluating an invented name. The term animal population was intended to indicate if a sub-category of the target species is specified such as piglets less than x weeks and this is now amended in the guideline.
	We think the aspects for assessment are quite impractical. What does the EMEA consider the animal population? How will potential harm in case of mix-up be assessed? This knowledge is essential if the applicant is to follow the suggestion in the second paragraph of section 2.	EMEA to clarify. Risk of inappropriate medication to the animal can be assessed by a) lack of the appropriate mediation, and b) risk from the incorrect medication
	Although the EMEA already refuses in practice proposed names of veterinary products on the basis of similar names of pharmaceutical products (and vice-versa), this written rule would confirm a situation which is not acceptable. In fact, trade mark owners in the pharmaceutical business easily grant authorisations to other companies to use quite similar names in the veterinary business and reciprocally trade mark owners in the veterinary field usually act accordingly with regard to similar names in the pharmaceutical field. Moreover, such a wording was not included in the last proposed revision of the Guideline for Pharmaceutical products, which could make people think that in the pharmaceutical field, the EMEA only checks proposed names with similar names of pharmaceutical products and not veterinary products.	Proposal: "~~*…(either a veterinary medicinal product or one for human use)".*~~ As already indicated above this is accepted.

Page 5, Section 2.3.1, 1st paragraph	**INTA** The restriction of an invented name to one word to be an arbitrary and unjustified restriction on a trademark. A trademark composed of more than one word is acceptable in almost all trademark offices throughout the world, if there is no confusion with existing trademarks. A trademark consisting of more than one word may also be of assistance in preventing confusion. As the Guidance, uses the word preferably, it would be appreciated if clarification could be given as to when a trademark of more than one word would be acceptable. This provision should also not be used to deny the use of a trademark on a dosage form or device used in conjunction with a trademark used on the pharmaceutical preparation. The use of a trademark for dosage forms or devices allows consumers to distinguish effectively between the different medicinal products and reduces the risk of confusion.	This is accepted.
Page 5, Section 2.3.4	**INTA** Clarification is required as to the relationship of the proposed/approved trademark registration and the use of upper-case letters. Trademarks are registered in all block letters and such registrations provide the right to use such trademarks with all block letters or with initial capitals. Additionally, as the Introduction to the Guidance states that …*"[t]he review of trademarks is not under the EMEA remit since other authorities are responsible for such procedure both at the National and European level,"* a requirement solely related to the trademark registration is inconsistent.	This point is now deleted from the guideline.
2.3.5	**IFAH-Europe** It should be possible to use parts of the invented name for the fixed combination (e.g. the same 'stem').	Proposal: "*The invented name of a fixed combination medicinal product should be sufficiently different from those of the individual active substances and/or those of other fixed combinations containing the same active substance(s).<u>It is possible to use the same stem for the invented name of the</u> <u>fixed combination product as for a product containing only one active substance (mono product), independent of whether the mono product has been authorized by Centralised Procedure, Mutual Recognition Procedure, or Decentralised Procedure. However</u>, CVMP recommends applicants/MAHs not to insert the whole invented name of the individual active substance(s) in the proposed invented name for the fixed combination.*"

		The text as currently written does not preclude that the same stem is used providing there is still sufficient differentiation between the invented name of the fixed combination medicinal product and the individual active substances and/or those of other fixed combinations containing the same active substance(s). Therefore, proposal not accepted.
2.4.5	**IFAH-Europe** The official MAH name should be the corporate name (e.g. 'My company') and should not include the suffixes added (e.g. 'My company International A.H.').	Proposal: "*The 'name of the MAH' of the medicinal product should correspond to the official name of the MAH as presented in the proof of establishment of the applicant/MAH (excluding suffixes).*" This point is now addressed in the guideline.
Page 8, Section 4.1.2, 2nd paragraph	**INTA** The Guidance states that...*"It should be noted that invented names(s) may be checked against authorized, applied for, suspended and revoked/withdrawn medicinal products in the different Member States according to the relevant national legislation."* Although we agree that similarity to recently suspended, revoked or withdrawn products may be of significance, there should be a specific time frame as to the number of years that products no longer in the marketplace will be considered. For the sake of predictability for the applicants of marketing authorizations and to avoid unnecessary rejection of names on the basis of very old inactive marketing authorizations, EMEA should only consider names used in revoked/withdrawn marketing authorizations for a defined period of time following the date of revocation/withdrawal. Article 19 of The World Trade Organization's Agreement on Trade-related Intellectual Property Rights proposes that three years of non-use should have occurred before cancellation of a trademark can take place. Consequently, three years non-use of a trademark is now recognized in national trademark law as sufficient basis for a cancellation action. We recommend the adoption of three years as the defined time period. However, even if three years is not an acceptable period to EMEA, a defined period is recommended.	It should be noted that this is only a recommendation.
4.1.5	**IFAH-Europe** According point 3 if no name is accepted, the Marketing Authorisation is granted with an INN name and the applicant is forced to submit a variation afterwards (c.f. section 4.1.6.1). This is not acceptable. A referral procedure could be more useful than to submit a variation.	Please allow the option for an arbitration procedure. The Applicant has the rights of appeal as described in this section. A referral procedure is not the correct legal provision to address such a situation.

4.1.6.2	**IFAH-Europe** *"In addition, with each PSUR, a summary report on medication errors, including those due to name confusion, occurring with the product should be submitted in accordance with the guidance provided in Volume 9 of the Rules Governing Medicinal Products in the EU"* In such cases, report to the VMPname@emea.europa.eu is sufficient, If no ADR is recorded, there is indeed no requirement to enter such information in the PSUR.	Please delete this paragraph: ~~*"In addition, with each PSUR, a summary report on medication errors, including those due to name confusion, occurring with the product should be submitted in accordance with the guidance provided in Volume 9 of the Rules Governing Medicinal Products in the EU"*~~ Accepted. However discussion will take place in Pharmacovigilance Working Party in the context of Volume 9.
5.	**IFAH-Europe** EMEA is asked to explain the intention and purpose of this section.	EMEA to clarify. The intention is to provide information on the outcome of invented names which has not been the case to date. This is consistent with the human approach and allows the industry to see the basis for such decisions.