Guideline

Central Administration for Pharmaceutical Products
General Administration of Veterinary Pharmaceuticals

GUIDELINES ON
NAMING OF VETERINARY PHARMACEUTICALS
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1. Introduction

1.1 Objective

This document is developed to provide a clear guidance for companies on the criteria that need to be considered when selecting the invented names for medicinal products intended for veterinary use, to reduce medication errors and for safety issues.

1.2 Background

The checking of the proposed (invented) name is a part of EDA's role in evaluating the safety of veterinary medicinal products within the authorization procedure, as the invented name could create a public health concern as a potential safety risk.

Careful considerations should be given to the name in order to minimize the risk of mix ups between different products.

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 authorization holder".

The applicant would be expected to review the proposed invented name, applying the criteria outlined in this guidance, before requesting that an invented name to be considered.

Approval of a trade name by the authority does not relieve the company of its responsibility when potential hazards occur after marketing of the product.

The applicant/MAH is sole responsible for checking all legal requirements and criteria for trademark registration and ownership.

1.3 Scope

The scope of this guidance is to provide applicants with information about criteria applied when reviewing the acceptability of names intended for veterinary use.

2. Definitions & Abbrevitions

MAH: Marketing Authorization Holder

Invented name is the trade name of a medicine.

INN (International Nonproprietary Name) is a unique name that is globally recognized and is public property, developed by World Health Organization to facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. It is also known as a generic name.

USAN (The United States Adopted Names): are unique nonproprietary (generic) drug names developed by The United States Adopted Names (USAN) Council.

INN/USAN stem: Stems define the pharmacologically related group to which the INN/USAN belongs.

Ex: (-mycin) stem stands for antibiotics, produced by Streptomyces strains ex: erythromycin, gamithromycin, kanamycin, kitasamycin, lincomycin, neomycin, paromomycin, salinomycin, spiramycin, spectinomycin, streptomycin, tulathromycin, azithromycin, dihydrostreptomycin, clarithromycin, clindamycin.

The common name is the name of the active substance contained in the product; is the INN (International Nonproprietary Name) or, if an INN does not exist, the usual common name.

An umbrella segment of an invented name is a section of invented name that is used in more than one medicinal name to create a brand or range of products.

Qualifiers are relevant words or parts of words (abbreviations) that have an information content that is closely related to a medicinal product.

3. Criteria Used in Assessing the Suitability of Invented Names for Use in Veterinary Medicines

3.1 General Criteria

3.1.1 The same invented name must be used during a "Line-extension".

3.1.2 Obtaining a trademark for the proposed trade name is not considered justification for accepting a proposed trade name.

3.1.3 An invented name for a medicinal product shall primarily consist of one word.

3.1.4 The invented name cannot be too general like "Analgesic tablets".

3.1.5 The invented name of a medicinal product should not be comprised wholly of initial letters (acronyms) or abbreviations nor include punctuation marks.

3.1.6 The invented name should not be a real word, i.e. have a meaning, including known names, and it should not be significantly similar to the known word in English or in other language (e.g. Galaxxy). Exception to this rule is that the name of a medicinal product can include a registered trademark or the name of the marketing authorization holder.

3.1.7 The strength

- The unit microgram must be written out to avoid confusion with the unit mg.

- The same unit should be used within a product range.

- The strength can be expressed in weight, weight per unit volume, weight or dosage, or in percentage. However, Expressing the product strength as "%" is not endorsed. Single dose or multiple dose container has an impact on the expression of the strength.

- The declared dosage should correspond to the dosage of the innovator.

- Whole numbers should be used whenever possible.

3.2 Safety concerns

3.2.1 The invented name of a medicinal product should not have potential look-alike and sound-alike (LA/SA) similarity, which could cause confusion in print, handwriting or speech with the invented name of another medicinal product or common name or excipient.

3.2.2 In general, there should be a difference of at least three letters. Even though two names have three or more different letters, they may still cause confusion. On the other hand, names that only differ by two letters may – in a few cases – be sufficiently different to not cause any confusion

3.2.3 Since the beginning and end of a word are most memorable, a similarity between the beginning and the end of names is particularly important.

3.2.4 If there is an orthographic and/or phonetic similarity, the likelihood of confusion and its possible effects are assessed, taking into account the following:

- The prescription status.
- The indication and condition of supply.
- The dosage form.
- The type of application.
- Side effect profiles.
- Contraindications.
- Effect of not taking/not using (e.g. antibiotics, immunosuppressants).
- Possibility of incorrect route of administration.
- Potential new pharmaceutical forms and/or routes of administration for the medicinal product concerned, as well for the other medicinal products with a similar invented name.

Example: the degree of similarity in names is no longer acceptable, e.g. in the case of two oral dosage forms with active substances which are contraindicated for one another.

3.2.5 The invented name of a medicinal product should not include the full invented name or significant portion of another medicinal product.

3.2.6 The invented name should not incorporate medical abbreviations (e.g., QD, BID) or others commonly used for prescription communication because the incorporation of such Abbreviations could inadvertently be a source of error.

3.2.7 The invented name of a medicinal product should not convey a promotional message. An (invented) name is considered promotional if it makes claims relevant to:

- Overstatement of product efficacy.
- Minimization of risk.
- Broadening of product indication.
- Unsubstantiated superiority claims.
- Being overly fanciful.

For example, a proposed proprietary name for a chronic disease contains or sounds like "cure," it would overstate the clinical benefit by misleadingly implying that the product can cure the chronic condition.

3.2.8 The invented name of a medicinal product should not be misleading with respect to the qualitative or quantitative composition, or the pharmaceutical form. Applicants should consider the future life-cycle of the medicinal product, and post-authorisation changes which may lead to discrepancies between the product profile and the invented name.

- The invented name is misleading with respect to the composition and therapeutic effects of the medicinal product if it is too similar to or derived from the name of an ingredient which is not contained in the product, or if

the name contains an INN/USAN stem reserved by the WHO/USAN Council for a group of substances into which the active substance contained in the product does not belong.

- The invented name is misleading with respect to the therapeutic effects of the medicinal product if it contains indications which are not described in the Summary of the Product Characteristics, or it highlights only one of many indications or target species.

- If the medicinal product contains more than one active ingredient, the invented name should suggest all the ingredients, not just some of them, or it may be considered misleading.

3.2.9 That invented names that look or sound like other medical terms, diagnostic tests should be avoided.

3.2.10 Applicants should consider the phonetic characteristics of an invented name and the potential difficulties in pronunciation. Ex.:

- The name should be easy to pronounce.

- The use of repeated vowels or consonants in the prefix of the invented name should in principle be avoided.

- Very short invented names composed of, for instance, a string of vowels or consonants may be inappropriate to identify medicinal products.

- In addition, applicants should give due consideration to any other element which may hamper readability and identification of the product.

3.2.11 If the invented names are considered too long to be accommodated on very small Containers, they may be rejected.

3.2.12 The invented name of a medicinal product should not incorporate product-specific attributes such as:

- Dosing intervals (e.g. NameBID).

- Dosage form (e.g. NameTab).
- Route of administration (e.g. Nameoral).
- Manufacturing characteristics (e.g. "NameLyophylized").

Avoiding the suggestion of a product-specific attributes such as dosage form or route of administration in the name will enable a company to use the same proprietary name for future dosage forms of the product without making the proprietary name misleading. For flexibility in product development, it may be advisable to limit the inclusion of such attributes in the proposed proprietary name.

3.2.13 The name of the medicinal product should not be identical with the names of human medicinal products, food supplements, cosmetic products or other products.

3.2.14 However, even though the name of the medicinal product had been previously assessed as not liable to confusion for a specific pharmaceutical form, it does not mean that it will be automatically acceptable for another pharmaceutical form because such a name – from a practical point of view – may have different parameters when assessing the potential for confusion.

3.2.15 The use of common error-prone abbreviations in a proprietary name may be misinterpreted and therefore should generally be avoided (www.ISMP.org/tools/errorproneabbreviations.pdf).

3.2.16 Incorporation of Company's Name:

- Invented name should not incorporate the manufacturer's full name or part of the name across multiple products, as this may increase the similarity of invented names by the same company (e.g., "ABCName1," "ABCName2," "ABCName3").
- If the company submits a brand name attached to the **company's abbreviation** either on the beginning or at the end of the name this will be rejected.

3.2.17 Use of Symbols:

- EDA discourages applicants from using symbols (i.e., "+" or "&") to link components in proprietary names because symbols can be misinterpreted or confusing (e.g., "+" can be read as "4"). Therefore, EDA encourages using words rather than symbols.
- Other symbols (-, =, *, #, „®", „©", „™ etc.) are not acceptable.

3.3 Use of International Nonproprietary Names (INN) or United States Adopted Name (USAN) in invented names.

3.3.1 Applicants are advised to take into consideration World Health Organisation (WHO) resolution (WHA46.19), where appropriate, i.e. "It would therefore be appreciated if invented names were not derived from international non-proprietary names (INNs) and if INN stems were not used in invented names". Applicant are strongly advised to take account of WHO recommendations that invented names should not be derived from INNs, especially an INN stem. Hence, the substantial closeness of the medicinal product name either in speech, print or handwriting with its own or a different INN is not endorsed.

3.3.2 The invented name should not incorporate INN/USAN stems in the position that WHO/USAN Council designates for the stem (e.g., Drugofenicol contains the stem "-fenicol" in the position that WHO/USAN Council designates for that stem) as this can result in the creation of multiple similar proprietary names and/or proprietary names that are similar to established names, leading to an increased risk of medication errors because of name confusion.

3.3.3 The use of a two letter INN stem in an infix or suffix position in an invented name will be addressed on a case by case basis.

3.3.4 The Applicant is expected to review INN similarity or INN/USAN stem inclusion use before requesting that the proposed invented name(s) be considered.

3.3.5 Applicants should screen proposed proprietary names against the stem list created by the WHO/ USAN Council to ensure INN/USAN stem is not present in the stem position in the proprietary name.

Tools:

https://poca-public.fda.gov/usan_search

https://extranet.who.int/soinn/

3.3.6 Where the Applicant wishes to use the INN or common name:

- The INN or common name should be together with the name of the MAH (MAH name must comply with that mentioned in Commercial register). The company has two options to include MAH name with the common name:

  - MAH name beside the common name:
    INN/Common name-MAH name

  - MAH name below the common name:
    INN/Common name
    MAH name

- The INN name and the MAH name cannot be used together in a single word (ex: Xtiamulin).
- In case the active substance is present in authorized products in more than one form (base, salt, ester), EDA recommends that common names of medicinal products containing various forms of the active substance are distinguished by specifying the particular salt/form of the active substance in the name of the medicinal product.
- In case the active substance is present in authorized products in one form only, it is not necessary to distinguish the names by specifying the particular salt in the name of the medicinal product.
- In case of a fixed combination of two or more active substances:
  - ✓ EDA recommends to separate the names of the active substances in the common name of the medicinal product with a slash (/).

- ✓ If the strength of individual components of the fixed combination product is expressed in units of volume, EDA recommends to separate them in the expression of strength (as part of the full product name) with the symbol plus (+).

Examples:

Acceptable:

Tulathromycin/Ketoprofen MAH followed by the strength 100 mg/120 mg
Tulathromycin/Ketoprofen MAH followed by the strength 100 mg/mL + 120 mg/mL

Nonacceptable:

Tulathromycin + Ketoprofen MAH 100 +120 mg

Tulathromycin-Ketoprofen MAH 100/120 mg/mL

3.4 Criteria Used in Assessing the Acceptability of Umbrella Segments of Product Names:

3.4.1 An umbrella segment of an invented name is a section of invented name that is used in more than one medicinal name to create a brand or range of products.

3.4.2 Where an umbrella segment is proposed to be used for more than one product, the umbrella segment should not be used if its use is likely to result in safety or efficacy concerns resulting from confusion between the products sharing the same umbrella segment. and applicants are encouraged to develop new product names without umbrella segments for each product. Such concerns may arise, for example:

– if the products contain different active ingredients;

– if the products can be used in different populations;

– if their safety profile is different in different populations.

– if their interactions are different;

– if their features of and treatment for overdose are different;

– if their speeds of onset are different.

3.4.3 The first name (used/authorised for the first time) should be without any qualifier.

3.5 Criteria Used in Assessing the suitability of qualifiers /abbreviations:

3.5.1 Qualifiers are relevant words or parts of words (abbreviations) that have an information content that is closely related to a medicinal product.

3.5.2 An Invented names and qualifiers should always be separated by a space.

3.5.3 Proposed qualifiers should not consist of a single letter or number (Arabic and Roman), because they may be confused with the strength and/or posology of the medicinal product. Numbers in general should only be used to indicate the strength of the medicinal product. In certain cases, a number(s) may form part of a qualifier; however, this would be assessed on an individual basis.

3.5.4 The following should be taken into account when proposing a qualifier/abbreviation:

- Whether the qualifier/abbreviation provides further information on characteristics of the medicinal product (e.g. duration of action, device, route of administration, composition, patient population) or provides for a differentiation, which may help healthcare professionals and/or patients to prescribe/select the appropriate medicinal product.

- The potential risk to public health in case of a medication error potentially related to the qualifier/abbreviation versus the potential risk resulting from a more complex name or completely different name should be assessed.

- The EDA strongly encourages applicants to develop new product names without umbrella segments for each new product. The proliferation of multiple products with similar but not always identical active substances using connected names may

result in confusion among healthcare professionals and possible inappropriate use of these medicinal products.

- The umbrella segment should not be used for a different product where there is a significant difference in active substance(s).

3.5.6 Applicants should provide in all cases an explanation on the inclusion of the qualifier.

Examples:

Comp, compositum, comb, Plus (contain more than one active ingredient)

Duo (contain two active ingredients)

Forte (higher dose than other medicinal products in a product range)

Small dogs-Medium dogs-Big dogs

LC (for preparations for intramammary use in cattle during lactation)

TS or DC (for preparations intramammary use in non-lactating cattle)

Flavour

For prolonged release preparation:

CR – Controlled release.

LA – Long acting.

PR – Prolonged release.

SA – Sustained action.

SR – Sustained release.

XR – Extended release.

XL – Prolonged release, once daily dosing.

MR – The use of MR for a prolonged release preparation is no longer recommended. Modified release can indicate a gastro-resistant product or a prolonged release product, therefore the term is not specific for an individual product.

For Gastro-resistant Preparations:

EC – Enteric Coated.

GR – Gastro Resistant.

4. Reuse of Proprietary Names:

4.1 If a medicinal product has never been marketed, its name can (after cancellation/name change) be used for another medicinal product.

4.2 If a medicinal product was on the market, the name can usually be reused five years after its cancellation/name change, unless it is a well-known name which, due to its level of awareness, could lead to a misleading assumption (active substance, indication...). EDA shall always consider the time for which the product has been on the market, how well it has been known to the public, what risks might arise from potential confusion of the products.

4.3 The use of a product name that may be confused with the name of a product whose marketing authorisation has been revoked or a product that has been recalled from the market, when products with identical active substance, identical or very similar indications, contraindications, interactions, etc. are concerned, is possible. EDA shall always consider what risks might arise from possible product confusion.

4.4 Where a product with an older name has never been placed on the market, its name may be used also for another active substance (and another MAH), if other rules specified in this guideline are met.

5. Post-authorisation issues related to invented names

5.1 Applicants should consider the future life-cycle of the medicinal product and post-authorisation changes which may lead to discrepancies between the product profile and the invented name. Changes to key aspects of the product profile which may have an impact on the acceptability of a name should be communicated by EDA Veterinay Naming Unit.

5.2 Medication errors resulting in dispensing and administering the wrong drug can occur when a proprietary name for a product marketed in the Egypt is identical, or nearly identical in spelling and pronunciation, to the proprietary name of a foreign product containing an entirely different active ingredient marketed only in a foreign country.

5.3 If a marketed product's trade name causes medication errors, the company should work with EDA to resolve the situation. If the product does not comply with applicable requirements and the company is unwilling to resolve the issue, the company may be subject to enforcement actions.

6. For Imported medicines:

The name of imported medicine must be identical as the name in the country of origin. The name must not be translated unless it contains a word belonging to one of the national languages.

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