GUIDELINES ON Naming of Human Pharmaceutical Products

2024

DRAFT

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Central Administration of Pharmaceutical Products (CAPP)
General Administration of Human Pharmaceuticals Registration (Hum.PR-GA)
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Executive summary

The fourth version of the naming guidelines replaces traditional letter-count method with more advanced approach using phonetic and orthographic similarity score using the EDA Naming Checker Tool. This update also incorporates the consideration of the international non-proprietary names (INN) and U.S. Adopted Names (USAN) in reviewing proposed trade names. The guidelines provide detailed procedures for evaluating proposed trade names, ensuring that they are not confusingly similar to existing names and that they are not likely to cause safety concerns or negative connotations.

1. Introduction

1.1. Objective

EDA is issuing these guidelines to provide companies with the rules to develop trade names for the human pharmaceutical products. This guidance describes best practices to help minimize proprietary name-related medication errors. It also describes the procedure used by EDA to assess proposed trade names, which companies may use prior to submitting names for EDA assessment.

1.2. Background

Establishing a trade name is an essential first step in the design and development of drug products since, out of hundreds of products on the market, end users may rely, partially or entirely, on the trade name to determine which product is intended for or used by a particular patient.

The patient may receive the wrong medication or it may not be possible to identify the product used if end users find it difficult to distinguish a trade name from other drug names that are similar to it either phonetically (sound-alike names) or in spelling or orthographic appearance (look-alike names), or if the drug name is otherwise confusing or misleading.

As EDA has recognized, and addressed on numerous occasions, confusion involving trade names can cause or contribute to significant medication errors.

Our goal has been to create and share with the companies a transparent, standardized, and organized procedure for assessing trade names as they relate to product review, and approval process.

Final acceptance of a proposed trade name occurs as part of the approval of the drug product. Each name is evaluated on a case-by-case basis.

2. Safety Concerns

The purpose of reviewing the trade names is to minimize the risk of confusion with the name of another medicinal product. Obtaining a trademark for the proposed trade name is not considered justification for accepting a proposed trade name.

EDA recommends that companies avoid proposed trade names that are similar in spelling or pronunciation to existing proprietary names, established (or proper) names, or names of ingredients of other products.

EDA uses EDA Naming Checker tool to determine the similarity between names. Names with high similarity scores are more likely to cause confusion and medication errors. Generally, names that are nearly identical in spelling and/or pronunciation generate a similarity score of 70% or higher on the EDA Naming Checker tool.

3. Assessment the Proposed Trade Name for Attributes that could potentially contribute in Medication Errors.

Concerning and This section describes the attributes of proposed trade names that EDA usually finds that can usually be recognized during preliminary assessment by Companies. Before proceeding further with a complete assessment of whether a name is likely to contribute with medication errors or other violations of the EDA Regulations.

3.1 Comprehensively recognizable Spelling and Pronunciation Similarities of Proprietary Names.

EDA recommends the companies to avoid proposed trade names that pronounce or are spelled similarly to already-existing trade names or names of ingredients in other products.

On the EDA Naming Checker tool, names with almost exactly comparable spellings and/or pronunciations typically receives a similarity score of 70% or higher and names with high similarity scores are more likely to result in confusion causing Medication Errors**.**

3.2 Combinations of Active Ingredients

Trade names of fixed combination drug products that include or suggest the name of one or more, but not all, of their active ingredients are opposed by the EDA because they may mislead the end user into assuming that the product only contains the ingredient or ingredients that are referred to by the name**.**

3.3 Inert or Inactive Ingredients

Since mentioning an inert or inactive ingredient in a proposed trade name could provide the false impression that the ingredient is of greater significance than its actual functional role in the formulation, we advise against doing so.

3.4 International Non-Proprietary Names (INN) and United States Adopted Name Stems

It is recommended for the companies to avoid using trade names that contain INN stems or United States Adopted Name (USAN) stems in the position that INN and USAN designates for the stem in a nonproprietary names.AS INN and USAN stems aim to convey a pharmacological or chemical property of a pharmaceutical products, and one stem may be used for a number of pharmacological products. Placing these stems in the trade names at specific position could give the false impression that a product has a pharmacological or chemical feature that it does not. The utilization of these stems within trade names can lead to the generation of several names that are similar to one another or to nonproprietary or existing names for other drugs leading to an increased risk of medication errors. According to the WHO and USAN, the well- established stem should not be used in or as trademarks

3.5 Family Branding (Family Trade Names)

The EDA refers to a naming method in this guidance as "family branding" when it involves using the same root trade name to identify several products that have at least one active ingredient (or active moiety) in common. This method involves giving the new product a unique suffix or modifier that differentiates it from the originally marketed product. Family trade names create a risk of medication errors if the modifiers do not adequately differentiate the products.

When assessing a proposed use of a family trade name for a product, EDA takes these factors into account on a case-by-case basis.

For Example: " Name", "Name DM", and "Name D", use a family branding strategy to Market drug products containing guaifenesin, utilizing the modifiers “DM” and "D" to convey the additions of dextromethorphan and the decongestant pseudoephedrine to the formulation.

Answers for these questions typically indicate a reduction in the risk involved in the family branding naming method.

- Does the first product marketed under the same root trade name have at least one active component or active moiety in common with the proposed product?
- Are there other marketed products using the same family trade name: are there any known cases of name confusion?
- Does the suggested modifier(s) significantly distinguish the proposed product from other products under the same family brand?
- Do other labeling factors, such as carton and container, effectively differentiate the products under the family brand?

3.6. Reusing Cancelled Trade Names

It is highly recommended by EDA that the companies avoid naming a different drug product with the brand name of a discontinued product since there is a significant possibility that end users will continue to link the name with the original cancelled product. Healthcare professionals commonly keep using the trade names of cancelled products. In the case that trade names are proposed for reusing, EDA will evaluate them case-by-case, taking into consideration factors that may establish drug name familiarity, such as the length and breadth of product distribution, the presence (or absence) of past or present generic equivalents, along with data that might otherwise suggest drug name familiarity among healthcare professionals. If a company decides to proceed using this naming method, we recommend considering the factors mentioned above and provide confirmation that it won't be complicated to reuse the trade name of a cancelled product.

3.7 Using Unpronounceable Letters and Numeric Characters in Trade Names

Since healthcare professionals utilize trade names when prescribing, ordering, transcribing, dispensing and administering drugs as well as when counseling patients on their medications, it is generally considered best practice for trade names to be pronounceable as words. We recommend companies not to providing trade names (e.g. laeme56) that are composed of a random combination of letters or numbers. These names might not be recognized as drug names, which are usually just letters, or they might be mistaken for another component of the prescription or drug product, such as the dosage or method of administration.

3.8. Names That Include Product-Specific Attributes

The EDA recommends companies not to include product-specific attributes in the proposed trade name (e.g., "NameLyophilized"), dosage form (e.g.,"Nametabs"), or route of administration (e.g., "Nameoral").as during a drug's development process, it is not uncommon for product-specific attributes to change in response to the introduction of new dosage forms. As this may cause the trade name to become inaccurate making it unusable for subsequent formulations of the product.

The EDA recommends evaluating the name if it contains references to product-specific attributes in the trade name to make sure the product-specific attribute is consistent with the terminology used on the product's label and does not raise the risk of medication error.

3.9 Medical Abbreviations

We recommend not using symbols, dose designations, and medical abbreviations that are frequently used for prescription communication in proposed trade names since doing so could inadvertently introduce a source of error.

The EDA recommends considering additional variables such as placement and presentation that may affect interpretation of the element into account when assessing a proposed trade name that includes an element that is also an abbreviation, symbol, or dose designation in order to ensure that the element's presentation in the name is not error-prone.

As an example, “ORO" is used as an abbreviation for oral route of administration; it is typically found at the beginning of the medicinal name. Since "ORO" is unlikely to be interpreted as a medical abbreviation when used at the beginning or within the root trade name (e.g., ORОname or NaORОme), it is not expected to increase the risk of medication errors. However, if "ORO" is used as a modifier (e.g., Name ORO or NameORO), there is a higher possibility that "ORO" will be interpreted as an abbreviation for the oral route of administration, which could lead to confusion if that is not the intended significance.

3.10 Modifiers as Components of a Trade Name

Some trade names are consisted of a base trade name that has additional words or components added to it; those are called modifiers. The modifier part of a trade name is usually separated from the trade name by a space or hyphen and consists of one or more letters, symbols, numbers, and/or words. It is placed at the end of the trade name. In order to differentiate between many products that have at least one active ingredient, companies often suggest a same root trade name with different modifiers.

Medication errors, such as administering and dispensing of the incorrect formulation, dose, strength, or frequency of administration, have been caused by confusion resulting from the use of modifiers in trade names. When a product is prescribed or dispensed without the differentiating modifier, medication errors have also happened within the same product line. And errors have been caused by inconsistent modifier utilization and the lack of standard meanings for certain modifiers intended to provide product information to the end user.

When using a modifier, EDA recommends companies to use one that already exists, has an obvious significance, and hasn't caused confusion. Examples of such modifiers are provided in Appendix A and are meant to convey the referenced significance.

Modifiers	Meaning
XR	Extended-release product
ER	Extended-release product
DS	Double strength
LA	Long acting
Depot	Depot injection
ODT	Orally disintegrating tablets

Appendix A: Examples of Previously Used Modifiers and Their Referenced significance

Companies should consider the following factors that can help in this assessment:

1. **General Considerations When Developing a trade Name That May Include a Modifier:**

Trade names involving the use of family trade names are assessed on a case-by-case basis. Every request for a proposed trade name which includes a family trade name will be assessed to see whether the:

A- Products share at least one active ingredient.

B- Products are differentiated by labeling (carton and container).

C- Modifier conveys accurate information about the product.

D-Modifier effectively differentiates the product from other products in the product line.

- **The product has a characteristic (such as an extended-release formulation) that is typically identified by a modifier:**

In some cases, even while no product with these characteristics is on the market under the same root trade name, a modifier referring to specific characteristics (such XR for extended-release formulations or ODT for orally disintegrating tablets) may be advantageous.

- **The risk of a medication error caused by omitting a modifier or alternatively from including a modifier**

In some cases, using a completely different trade name for a product is safer than using the same root trade name with a modifier . Such instances could occur if a product differs significantly from a marketed medication in terms of indications, usage, patient populations, doses, safety profiles, or methods of administration.

2. Special Considerations Related to Certain Types of Modifiers:

A- Descriptive modifiers

EDA refers to certain modifiers as descriptive modifiers as these are composed of letters or words that are intended to provide details about the composition or intended indication of the product.
(Appendix A contains examples of modifiers.)
When descriptive modifiers are confusing, misleading, or susceptible to misinterpretations there is a risk of medication errors.
The suggested modifier should be assessed to figure if the suggested modifier is already in use in the market and whether it has been used consistently with a commonly recognized meaning. And if there is an existing modifier with the same intended meaning, assess if the proposed modifier conveys the intended meaning more clearly than the existing modifier. If not, consider using an alternative modifier.

B- Use of Numbers and symbols in modifiers

In general, EDA recommends companies not to include numerals in their trade names. Numbers in Arabic and English have been confused with prescription medication products' strength, amount, duration, or class of prescription drug products.

C- Incorporation of the company's Name

EDA recommends companies to avoid proposed trade names that include all or part of the company's name across several products (such as "companyName1," "companyName2," or "companyName3"). This approach increases the possibility of Medication Error by producing a number of trade names that are similar to one another.

4. Further best practices for review, including for misbranding and other legal concerns

As a best practice, companies should avoid usage of trade name that could be liable to any violation of the EDA Regulations, even though our recommendation focuses primarily on characteristics of trade names that can contribute to medication error. And if a trade name is inaccurate or misleading—for example, through offering false claims about safety or efficacy. For example, a proposed trade name that contains cure or that sounds like cure for a drug that treats the symptoms associated with a chronic disease would be concerning. The word “cure” is defined as drug that stops a disease and makes someone healthy again. So, if a proposed trade 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.

Phonesesthemes (the sound of the name) and phonosemantics (the meaning transmitted by the sound of the word) are taken into consideration in addition to common morphological and semantic similarities when assessing if a name is misleading.

5. Recommended methods for assessing the risk of medication error caused by a proposed trade name's similarity to other names

The objective of EDA's trade name assessing process is to prevent medication errors by end users. The EDA takes into consideration an extensive number of potential sources of error when assessing a proposed Trade name, including orthographic, phonetic, and spelling similarities in addition to other sources of error referred to in other sections of this guidance.

The procedures that EDA utilizes to assess proposed trade names are clarified below, along with the steps that EDA recommends companies to take prior to submitting a proposed trade name for EDA evaluation.

5.1 Computational Method to Identify Names with Potential Orthographic, Spelling, and Phonetic Similarities

Using the EDA Naming Checker Tool, EDA assesses how orthographically and phonetically similar a proposed trade name is to other names.

EDA enters the proposed proprietary name into EDA's Naming Checker Tool and queries the proposed trade name against names in drug databases. Companies may include EDA Naming Checker Tool evaluation with their proposed trade names submissions.

Regardless of whether a company submits data from EDA Naming Checker Tool for EDA to consider in its review, EDA will independently conduct an assessment using EDA Naming Checker Tool to compare the proposed trade name to other proposed trade names submitted for products not yet approved. Such names are often confidential; therefore, it is possible that EDA may identify conflicts with the names of pending products that are not publicly known to other companies proposing trade names.

EDA recommends that companies screen their proposed proprietary names by conducting orthographic and phonetic searches using the EDA Naming Checker Tool developed by EDA.

The threshold EDA uses to conduct the orthographic and phonetic searches is set at a combined score of 55%. Based on our post marketing experience, the combined measure of similarity has been positively correlated to errors involving name confusion.

If the proposed name contains a modifier, first enter the root trade name without the modifier and group the names as described below. Then repeat this process using the root name and modifier.

EDA Naming Checker search will provide three data sets: (1) Combined orthographic and phonetic matches, (2) phonetic matches, and (3) orthographic matches. Companies should review the Combined orthographic and phonetic matches and group the name pairs into one of the following three categories:

- Highly Similar Name Pair: combined match percentage score ≥70%
- Moderately Similar Name Pair: combined match percentage score ≥55% to ≤ 69%
- Low Similarity Name Pair: combined match percentage score ≤54%

As a general principle, the higher the percentage assigned by EDA Naming Checker Tool, the greater similarity the proposed trade name has to the name identified by EDA Naming Checker Tool.
We expect names with high similarity scores to be more likely to result in confusion.

5.2 Assessing the Safety of Names That May Have Phonetic, Orthographic, or Spelling Similarities

Appendices B and C contain checklists that outline the criteria for evaluating the acceptability of the proposed trade name from a look-alike and sound-alike perspective. These checklists correspond to each of the three categories (Highly Similar Name Pair, Moderately Similar Name Pair, and Low Similarity Name Pair).

These checklists are intended to improve the predictability and transparency of the safety assessment of whether a proposed trade name is susceptible to confusion from a look-alike or sound-alike perspective.

- For highly similar name pairs, based on post marketing experience, we know that differences in product characteristics, including differences such as strength and dose, often cannot reduce the risk of a medication error. Therefore, trade name pairs that are highly similar (i.e. have a combined score of ≥ 70%) are at greater risk for a look-alike and sound-alike confusion.

- Moderately similar name pairs should be further evaluated to identify the presence of attributes that are known to cause name confusion.

o **Name attributes**: A major factor in name confusion is the first part of the drug's name. Furthermore, a significant contributing reason to drug name confusion is drug name pairs that share a beginning letter and at least three letters together in both names. To find the above features, we assess every pair of moderately similar names. We analyze these name pairs in more detail to find overlapping or similar doses or strengths.

o **Product attributes**: EDA is concerned about product name pairings that are somewhat similar and have overlapping or similar strengths or doses. On prescriptions, the dose and strength information are frequently found next to the drug name, and that information can be a significant factor that either increases or decreases the possibility of confusion. . EDA will review such name pairs further to determine whether sufficient differences exist to prevent confusion.

•Name pairs with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion.

-To summarize, the purpose of EDA's recommendations in this guideline is to assist companies in avoiding the selection of a trade name that could potentially lead to medication errors or other violations of the EDA Regulations. EDA takes into consideration any additional name-related data that the companies submit, in addition to the information and analysis about the trade name that are detailed in this guidance, while assessing a proposed trade name.

- Since trade name assessments are necessarily fact-specific, EDA makes its decisions by taking into consideration all available evidence and evaluating each case individually.

Appendix B: Highly Similar Name Pair Checklist

Highly Similar Name Pair Checklist (i.e., COMBINED Orthographic/Phonetic score is ≥ 70%)

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
	Orthographic Checklist		**Phonetic Checklist**
Y/N	Do the names begin withdifferent first letters? Note that even when names begin with different first letters, certain letters may be confused With each other when scripted.	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar when scripted or printed? EDA considers the length of names different if the names differ by two or more letters. This may be dependent on the position of the letters within thename and which letters are used. Some letters are more noticeable than others (e.g., "m" is a wide, noticeable Letter).	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there adifferent number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such as **vowel reduction**, **assimilation**, or **deletion**?
Y/N	Is there different numberor placement of cross-stroke or dotted letters present in the names?		
Y/N	Do the **infixes** of the name appear dissimilar when scripted?		
Y/N	Do the **suffixes** of the names appear dissimilar when scripted?		

Appendix C: Highly Similar Name Pair Checklist

Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69)

Step 1	Review the DOSAGE AND ADMINISTRATION of the Prescribing Information to determine whether strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are Moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (seeStep 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single-strength products, also consider circumstances where the strength maybe omitted. For any drug products comprised of more than one active ingredient, considerwhether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: o Alternative expressions of dose: for example, 5 milliliters (mL) may be listed in the Prescribing Information, but the prescription may express the dose in metric units (e.g., 500 milligrams (mg)) or in non-metric units (e.g., 1 teaspoon, 1 tablet/capsule). Similarly, a strength or dose of 1,000 mg may be expressed, in practice, as 1 gram, or viceversa. o Presence of trailing zeros or absence of leading zeros: for example, 10 mg (if written as 10.0 mg) is similar in appearance to 100 mg, which may potentiate confusion between a name pair with moderate similarity. Additionally, 0.1 mg can be confused with 1 mg if written without a leading zero (.1 mg) o Similar sounding doses: for example, 15 mg is similar in sound to50 mg.

Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences inthe names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.	
	Orthographic Checklist(Y/N to each question)	Phonetic Checklist (Y/N to each question)
	• Do the names begin with different first letters?	• Do the names have different number of syllables?
	Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar when scripted? EDA considers the length of names different if the names differ by twoor more letters. • Considering variations in scripting of some letters (suchas *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names	• Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation,or deletion?
	• Is there different number or placement of cross-stroke ordotted letters present in the names?	
	• Do the infixes of the nameappear dissimilar when scripted?	
	• Do the suffixes of the names appear dissimilar when scripted?	

6. References

- EMA Guideline on the acceptability of names for human medicinal products processed through the centralized procedure - revision 7 - 15/12/2023

- FDA Best Practices in Developing Proprietary Names for Human Prescription Drug Products. Dec.2020

- FDA Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products; Draft Guidance for Industry. Dec.2020

- MHRA Guideline for the Naming of Medicinal Products and Braille Requirements for Name on Label Jun.2019