Central Administration of Pharmaceutical Products (CAPP)
General Administration of Human Pharmaceutical Registration (GA-Hum- PR)

GUIDELINES ON
Naming of Human Medicinal Products
Year 2023

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1. Introduction

1.1. Objective

EDA is issuing these guidelines to provide companies with the rules to develop a trade name for medicinal Products which are not liable to be confused with the trade name of any other medicinal product to minimize the potential of prescription error.

1.2. Background

The name of the medicinal product may be a trade name or generic name accompanied by the name of the License holder or its abbreviation. 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 company would be expected to review the proposed trade name, applying the criteria of these guidelines, before applying a request for trade name selection.

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.

The trade name of a medicinal product should not be similar in spelling or pronunciation, which could cause confusion in handwriting or speech with the trade name of another medicinal product or generic Names.

3. Assessing the phonological and orthographic similarities

3.1. The trade name should not be liable to confusion with the generic or the trade name of any other medicinal product.

3.2. The proposed trade name must differ by at least 3 letters from the approved names with different generics, and 2 letters from the approved trade names with the same generics. In case of trade names that are different in writing and pronunciation, the number of different letters may not be considered.

3.3. Vowels are not considered as letters of differentiation if they have the same Pronunciation (A, E, I, O, U).

3.4. These letters (C,K,Q) –(F, PH, V)– (C, S, TH) – (O,U) – (I,Y,E) – (Z,X) – (D,T) – (B,P)

are considered same letter if they have the same Pronunciation.

4. Assessing the Suitability of Trade names for Use in Medicinal Products

4.1. Common non-pharmaceutical Names can't be used as pharmaceutical trade names, such as: Car brands, Food brands, Beverages.

4.2. Proposed Trade names which incorporate any meaning contrary to public morals will be refused

4.3. Trade names that are identical or similar to that of marketed foreign product containing an entirely different active ingredient are not allowed to be used even if the proposed product will be marketed only in Egypt.

4.4. Trade names shouldn't incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role. Example: Generic name: Ciprofloxacin HCL, Trade name: Ciprochloride (Refused)

4.5. Names containing sections which refer to dosage forms will be rejected.

Example: Generic Name& Dosage Form: Paracetamol tablets, Trade Name: cetatab (Refused)

4.6. Symbols and numbers are not allowed to be used in the trade names.

4.7. Names with sections that may refer to false composition, safety or therapeutic indications will not be approved.

Example: (neuro) in a compound does not refer to (Neurology)

Example: (gesic) in a compound which is not analgesic.

4.8. Names with Sections having specified meanings and have no scientific evidence will not be approved, such as: Safe, Pedi, Fast, Cure, etc.

5. Assessing the Suitability of Abbreviations

5.1. In case of presence of two products with same active ingredient but different in dosing intervals for the same company It might be appropriate for a trade name to incorporate a reference of the product's dosing interval such as name 12 hour & name 24 hour.

5.2. Sections - like: Co, Plus, Extra, … etc. - can be added to the Trade name only if there is an additional active ingredient added to the already approved product of the same Company. Example: Panadol Extra , Concor Plus, Ezapril Co

5.3. Any abbreviations that can be misinterpreted or confusing are not allowed to be used.

5.4. For drug - device combinations it might be allowed for the trade names to be associated with the medical device to differentiate between pharmaceutical products having the same active ingredient for the same company Example. Flixotide Diskus

6. Other

6.1. For imported products, only names marketed in the country of origin will be revised, in case of other name requested by the company it should be marketed in a reference country.

6.2. The trade names should be complied with the intellectual property law.

6.3. For approved trade names, it is not allowed for company to edit the name (Edition involves adding or removing dash or point in the trade name)

6.4. 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.

7. References

1- Guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure en – EMA 22 May 2014 Rev.6

2- MHRA Guideline_for_the_Naming_of_Medicinal_Products_and_Braille_Requirements_for_Name_on_Label June 2019.

3- Best Practices in Developing Proprietary Names for Non-Prescription Drug Products 2016-1296 Draft Guidance- FDA.Dec.2020

4- Best Practices in Developing Proprietary Names for Human Prescription Drug products.Dec.2020