FOOD AND DRUGS AUTHORITY

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Guideline on Naming of Medicinal Products

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No. 17 Indian Ocean Street, Nelson Mandela Avenue, Shiashie • Greater Accra • Ghana
P. O. Box CT 2783, Accra • GPS: GA-237-7316 • (+233) 302 233200 / 235100 • fda@fda.gov.gh

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15th March 2019	01	Initial issue
8th January 2024	02	General review of the Guideline in line with the current structure.

Acknowledgements

This guideline was developed based on the European Medicines Agency's Guideline on the acceptability of names for human medicinal products processed through the centralized procedure as well as FDA Guidance on Safety Considerations for Product Design to Minimize Medication Errors

Guideline on Naming of Medicinal Products
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Executive Summary

This guideline is developed in line with Section 118 subsection 8 of the Public Health Act, 2012 (Act 851), to serve as a guide for pharmaceutical companies to propose product names so as to identify and remedy potential sound-alike, look-alike confusion with existing drug names as well as meet current requirements before submission.

1. Introduction

This guideline is developed in line with Section 118 subsection 8 of the Public Health Act, 2012 (Act 851) which states as follows that a product name should not;

a) constitute a safety hazard,

b) be misleading,

(c) be established or based on international non-proprietary names, or

(d) it stems from a related substance or for any other sufficient reason determined by the Authority

One of the most possible outcomes of inappropriate product name has been associated with prescription and medication errors which may occur partly due to look-alike and sound-alike proprietary names, unclear label abbreviations, acronyms, dose designations, and error prone labeling and packaging designs. This guideline is thus developed in order to provide Applicants with clear guidance on naming for their medicinal products in line with acceptable international standards.

It is envisaged that this guideline will serve as a guide for pharmaceutical companies to propose product names so as to identify and remedy potential sound-alike, look-alike confusion with existing drug names as well as meet current requirements before submission.

The FDA may therefore request changes to a brand name if based on evaluation, it is deemed to potentially: -

a) constitute a safety hazard,

b) be misleading,

c) be established or based on international non-proprietary names, or

d) it stems from a related substance or for any other sufficient reason determined by the Authority

e) cause confusion with the name of an existing medicine;

Approval of the product name does not imply that the marketing authorization holder is absolved of any responsibility in the incidence that actual or potential adverse

reactions occur due to the brand name.

1.1 Legal Basis

This guideline focuses on recommendations for the proper labelling of all finished pharmaceutical products.

1.2 Scope

This guideline is applicable to all prescription and non-prescription medicinal products as well as medicinal products of biological origin.

The principles outlined in this guideline are also applicable for applications for variation of names of registered medicinal products.

2. Definitions and Abbreviations

In these Guidelines, unless the context otherwise states

- **Authority**: the Food and Drugs Authority established under Section 80 of the Public Health Act, 2012.
- **Brand name:** the proprietary name of the product**.**
- **Generic:** INN or common name.
- **INN:** international non-proprietary name.
- **Product:** a finished pharmaceutical product.

3. Criteria applied when reviewing proposed brand names

The criteria listed below should be seen as general principles. The criteria for acceptability of proposed brand names shall be based on public health concerns and in particular with regard to safety and applicable Laws and International Standards. Applicants should ensure that the proposed name complies with the criteria outlined in this guideline before submitting an application for name reservation or marketing authorization. Requirements and considerations taken during review are outlined hereafter:-

3.1 Safety concerns and other public health concerns in brand names

3.1.1 The brand name of a medicinal product should not be liable to cause confusion in print, handwriting or speech with the brand name of another medicinal product. When assessing the potential for such confusion, the following aspects are considered:

- The indication(s);
- The patient population(s);

- The pharmaceutical form(s);
- The route(s) of administration;
- The strength(s);
- The setting for prescription, dispensing and use;
- The legal status/classification for per the FDA Drug Classification list:
- Medicinal product subject to medical prescription;
- Medicinal product not subject to medical prescription;
- Medicinal product subject to special medical prescription;
- Medicinal product subject to restricted medical prescription;
- Medicinal product subject to special and restricted medical prescription;
- Orphan (designation) status;
- (Potential) New pharmaceutical forms, routes of administration and/or strengths for the medicinal product concerned, as appropriate.
- The degree of similarity versus the potential for harm to the patient in case of mix-up.

It should be noted that the FDA will consider potential for confusion of proposed brand names with already registered brand names of authorized, suspended and revoked/withdrawn medicinal products as part of the review process.

3.1.2 The brand name of a medicinal product should not convey misleading therapeutic and/or pharmaceutical connotations. This also includes brand names that 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.

3.1.3 The brand name of a medicinal product should not be misleading with respect to the composition of the product.

3.1.4 Consideration should be given to the phonetics and the potential difficulties a proposed brand name may create in terms of pronunciation in the official language of Ghana. Consideration should also be given to the fact that very short brand names composed of, for instance, a string of letters, may be inappropriate to identify medicinal products.

3.1.5 The use of qualifiers/abbreviations by letters as part of the brand name should in principle be acceptable on conditions.

Qualifiers consisting of a single letter or number(s) (Arabic and Roman) are discouraged, because they may be confused with the strength and/or posology of the medicinal product. However, the use of numbers may in certain cases be acceptable, e.g. vaccines (see section 4.3.1). The applicant may provide a justification for their inclusion.

The potential added benefit versus its potential risk to public health in case of medication error shall be taken into consideration when considering the acceptability of a qualifier/abbreviation. The following shall be considered:-

a) Whether the qualifier/abbreviation provides further information on characteristics of the medicinal product (e.g. duration of action, devices, route of administration, composition, patient population) without being misleading or provides for a differentiation, which may help healthcare professionals and/or patients to prescribe/select the appropriate medicinal product.
b) The potential risk resulting from more complex names, adversely affecting memorability, pronunciation and/or prescription of the medicinal product.

3.1.6 The brand name should not convey a promotional message with respect to the therapeutic and/or pharmaceutical characteristics and/or the composition of the medicinal product.

3.1.7 The brand name should not be offensive or have an inappropriate connotation in any of the official Ghanaian languages.

3.1.8 The brand name should not convey or suggest a spiritual association or be comparative, nor superlative in any way.

3.1.9 For a medicinal product containing a prodrug, a different brand name from the brand name of the medicinal product containing the related active substance is required.

3.1.10 The brand name should not comprise wholly of initial letters (acronyms) or code numbers nor include punctuation marks.

3.1.11 The importance of other elements such as labelling and pack design should be taken into consideration as contributing factors for the safe use of a medicinal product. These aspects should be discussed at the time of the review of mock-ups. The following are examples where labelling and pack design may play a role in the final decision of acceptability of brand names:-

a) The actual display of a brand name in the printed material may increase the level of similarity between two brand names or may convey a misleading connotation.
b) The labelling and pack design may support the meaning of a qualifier which otherwise would have been rejected.

3.2 Use of international non-proprietary names in proposed brand names

When proposing a brand name, Applicants are advised to take into consideration WHO resolution (WHA46.19), where appropriate*, i.e. "It would therefore be appreciated if brand names were not derived from international non-proprietary*

names (INNs) and if INN stems were not used in brand names".
Two types of INN concerns could be considered i.e. a potential similarity with its own or different INN or the inclusion of an INN stem into the proposed brand name(s). This can be both the prefix and suffix.
The Applicant is strongly advised to review INN similarity and/or INN stem inclusion before requesting that the proposed brand name(s) be considered for a medicinal product.
The FDA will review the above cases on the basis of WHO World Health Assembly resolution (WHA46.19) on protection of INNs/INN stems to prevent any potential risk of confusion between brand names and common names.

3.3 Product specific concerns in proposed brand names

3.3.1 For vaccines composed of several serotypes, when adding a new serotype the original brand name may be kept, it is recommended that the name is then followed by the number of serotypes present. The description of serotypes present is then listed in the qualitative and quantitative composition. An example of the format of the proposed brand name follows: Brand name + X [number of serotypes].

The same applies when different types of antigens are added. This is of particular importance in situations where both vaccines are simultaneously available on the market in order to allow differentiation of the products
3.3.2 For radiopharmaceutical medicinal products, the inclusion of target organs in the brand name should be avoided in order to prevent misleading connotations should an extension of the indication include new target organs.

In principle, numbers should not be used in the name to avoid confusion with the strength. In cases where the numbers appear in the radionuclide, these should be displayed in superscript, i.e., mass number Element + [brand name] Numbers included as part of commonly known abbreviations will be assessed on a case by case basis.

3.3.3 When reviewing the acceptability of brand names for orphan medicinal products, the same approach as for non-orphan medicinal products shall be applied. It is of particular importance in these cases to provide detailed information on the specific setting in which the product is dispensed and used as well as on the target population.
3.3.4 For non-prescription medicinal products, the use of qualifiers/abbreviations within the brand name should aid selection/identification/differentiation of the product by the patient and should minimize the risk of inappropriate use.

In view of the above considerations, the specific criteria as described under sections 4.1.5, 4.1.8 and 4.3.7 may not apply here.

In order to help self-selection and compliance by patients/consumers, it is acceptable that brand names have a positive connotation and/or be informative; labelling and pack design could be considered as contributing factors to this end. Carton and container labels are particularly critical for over-the-counter (OTC) medicines.

In case of a switch from "prescription" to " over-the-counter " status of an already authorized medicinal product it is up to the Applicant to choose whether to vary/extend the existing marketing authorization and consequently retain the same brand name or to submit a separate marketing-authorization application under a different brand name (see section 5). In exceptional cases, depending on the therapeutic context, the acceptability of the maintenance of the existing brand name may be further considered by FDA during the evaluation process.

3.3.5 For generic/hybrid/similar biological medicinal products the same criteria apply as for any other medicinal products in respect to the brand name. Special consideration should be given to the proposed brand name of a hybrid medicinal product to allow for differentiation when the latter differs in pharmaceutical form, strength, expression of active substance and/or indication from the reference medicinal product or other generics in the market.

3.3.6 Where the Applicant wishes to use instead of the brand name the common name or scientific name, together with a trademark or the name of the marketing-authorization holder/applicant, they should take into account the following rules:-

a) If an INN recommended by the World Health Organization exists for the active moiety it should be used within the name of the medicinal product exactly as published without omissions or abbreviations. All the linguistic versions of the INN, including translations officially recognized at the national level, shall be considered Page 6 of 10 to be the same name. If one does not exist, the usual common name should be used.
b) If a Modified INN (INNM) recommended by the World Health Organization exists for the active moiety, it should be used within the name of the medicinal product exactly as published without omissions or abbreviations.
c) Where the active moiety is an unpublished INNM the name of the medicinal product should be that as agreed by users of INNs (pharmacopoeia, regulatory

bodies, stakeholders), in accordance with the WHO INNM working document 05.167/3.

d) The 'name of the MAH' within the name of the medicinal product should correspond to all or part of the official name of the MAH as presented in the proof of establishment of the applicant/MAH.
e) For consistency reasons, ease in prescription by healthcare professionals and database entries, punctuation marks in between the INN and the name of the Company/trademark are not acceptable (with the exception of fixed combinations, where multiple INNs should be clearly separated by slash '/').
f) The proposed brand name should either be a brand name, or the common name accompanied by a trademark or the name of the MAH.

3.3.7 The brand 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). The whole brand name of individual active substance(s) should not be inserted into the proposed brand name for the fixed dose combination.

3.3.8 As multiple applications can have an independent life (e.g. may develop a different indication at a later stage), the proposed brand names of such applications should not lead to confusion.

4. Regulatory aspects related to the acceptability of proposed brand names

Brand names for variation/extension/ applications should be the same as those of the existing medicinal product. The addition of a qualifier to an already approved brand name constitutes a different brand name, which would require submission as a new marketing authorization application.

In case the applicant wants to submit a separate marketing-authorization application for, e.g., a new indication, a different brand name shall be used.

The FDA may request the MAH to change the brand name of an already approved medicinal product if the approved brand name is deemed inappropriate.

4.1 Change of the brand name

The brand name can also be changed at a post-authorization stage through an application for variation if the MAH wishes to change the name. Post-authorization procedural requirements are outlined in the FDA *Guidelines on Variations on Registered Finished Pharmaceutical Products.*

4.2 Report of prescription errors/medication errors due to the brand names of medicinal products:

The marketing authorization holder is responsible for reporting any adverse drug reactions resulting from:-

a) Prescription errors/medication errors due to the brand name of the medicinal product (example mix up with another medicinal product resulting into an ADR).

b) Misuse and/or abuse of a medicinal product caused by misleading therapeutic connotations of the brand name.

The ADRs should be reported in accordance to the procedures and guidance stipulated in the *relevant FDA Guidelines on adverse drug reaction reporting.*

References and Useful websites

1. Guideline on the acceptability of names for human medicinal products processed through centralized procedure
2. WHO website: http://www.who.int/en/
3. Information on INNs: http://apps.who.int/medicinedocs/en/d/Jh1806e/5.html
4. FDA Guidance on Safety Considerations for Product Design to Minimize Medication Errors: Guidance for Industry