

# **African Medicines Regulatory Harmonisation (AMRH)**

**Evaluation of Medicinal Products Technical Committee (EMP-TC)**

## **APPLICANT'S HANDBOOK**

**Guidelines on Recommendation for Naming of Medicinal Products to NRAS**



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## 1. Introduction

Prescription and medication errors may occur partly due to medicinal products having sound-alike or look-alike brand names, unclear labeling or poorly designed label artwork. Hence this guideline was developed in order to provide Applicants with clear guidance on how to choose brand names for their medicinal products.

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

- (a) cause confusion with the name of an existing medicine;
- (b) mislead as to the composition of the product or the use;
- (c) or otherwise, unsafe.

Approval of the 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.

Specific Country legislations in particular trade laws, should be taken into consideration while proposing a specific brand name.

## 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.

## 3. Acknowledgments

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.

## 4. Criteria to be considered when reviewing proposed brand names.

The criteria listed below may be seen as general principles. NRAs may develop additional guidance on specific topics based on their experience and may apply additional requirements not listed in this document during review of proposed brand names.

The criteria for acceptability of proposed brand names should be based on public health concerns and in particular with regard to safety.

Applicants should ensure that the proposed name complies with the criteria outlined in this guideline before submitting an application for Registration. Requirements and considerations taken during review are outlined hereafter: -

### 4.1 Safety concerns and other public health concerns in brand names

4.1.1 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 may be 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 supply:
  - 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;
- 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.

The NRAs may consider potential for confusion of proposed brand names with the brand names of authorized, suspended and revoked/withdrawn medicinal product.

- 4.1.2 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.
- 4.1.3 The brand name of a medicinal product should not be misleading with respect to the composition of the product.
- 4.1.4 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 a specific country.
- 4.1.5 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 in certain settings.

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). The applicant may provide a justification for their inclusion.

The potential added benefit versus its potential risk to public health in case of medication errors 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 applicability and use of the qualifier across all official languages. Qualifiers or abbreviations should not require translation to provide further information in the users.

(c) The potential risk resulting from more complex names, adversely affecting memorability, pronunciation and/or prescription of the medicinal product.

4.1.6 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.

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

4.1.8 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.

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

4.9.10 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.

## 4.2 Use of international non-proprietary names in proposed brand names

When reviewing a proposed brand name, NRAs 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).

The NRAs are advised to review INN similarity and/or INN stem inclusion before approving the proposed brand name(s) for a medicinal product.

The NRAs should 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.

### 4.3 Product specific concerns in proposed brand names

- 4.3.1 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.

- 4.3.2 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.

- 4.3.3 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.

- 4.3.4 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. (Revise sections to fit the new document)

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 non-prescription medicinal products (general sale and over the counter).

In case of a switch from "prescription" to "non-prescription" status of an already authorized medicinal product it is up to the Applicant to choose whether to vary/extend the existing registration and consequently retain the same brand name or to submit a separate 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 the NRA during the evaluation process.

- 4.3.5 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.

- 4.3.6 Where the Applicant intends to use the common name or scientific name (instead of the brand 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 to be the same name. If one does not exist, the usual common name should be used.

(b) If a Modified INN (INN<sub>M</sub>) 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 INN<sub>M</sub> the name of the medicinal product should be that as agreed by users of INNs (pharmacopoeia, regulatory bodies, stakeholders), in accordance with the WHO INN<sub>M</sub> 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. The INN name should be prominent.

(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 name should either be a brand name or the common name accompanied by a trademark or the name of the MAH.

4.3.7 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.

4.3.8 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.

## **5. Regulatory aspects related to the acceptability of proposed brand names**

Brand names for variation/extension/duplicate 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 new registration 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 NRAs may request the MAH to change the brand name of an already approved medicinal product if the approved brand name is deemed inappropriate.

### **5.1 Change of the brand name**

The brand name can also be changed post-authorization through an application for variation following specific NRAs requirements

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

The MAH 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 specific NRAs procedures and guidance .

**References and useful websites (Should be updated in line with references used in the text)**

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>