الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Guidance for Naming of Medicinal Products

Version 2.1

Date of issue	08 October 2015
Date of implementation	25 February 2020

Guidance for Naming of Medicinal Products

Version 2.1

Saudi Food & Drug Authority

Drug Sector

For Inquiries Med.Drug@sfda.gov.sa

For Comments Drug.Comments@sfda.gov.sa

Please visit SFDA's website at
https://www.sfda.gov.sa/en/regulations?tags=2

for the latest update

Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

Version	Author	Date	Comments
Draft	Executive Directorate of Pharmacovigilance	8 October 2015	-
1.0	Executive Directorate of Pharmacovigilance	25 February 2020	Final
2.0	Executive Directorate of Pharmacovigilance	04 January 2021	Update (Next page shows the updated details)
2.1	Executive Directorate of Pharmacovigilance	06 April 2021	Update (This version doesn't include any scientific update)

What is New in version No. 2.0?

The following table shows the update to the previous version:

Section	Description of change
Page No. 10	▪ Obvious Similarities in Spelling and Pronunciation of Proprietary Names
Page No. 10	▪ Inert or Inactive Ingredients
Page No. 11	▪ United States Adopted Name (USAN) Stems
Page No. 16	▪ Incorporation of Company's Name
Page No. 17	▪ Biological Products
Page No. 18	▪ Factors to be addressed in Applications

What is New in version No. 2.1?

- This version doesn't include any scientific update (format change).

Table of Contents

ACRONYMS & GLOSSARY

Cross-strokes	A line or stroke across something, as across the letter “t.”
Dotted letter	Having a pattern of dots, as in the lowercase letter “i.”
Down stroke	A stroke normally made in a downward direction
High alert medications	Drugs that bear a heightened risk of causing significant patient harm when used in error**.**
INN	International Non-proprietary Names
LASA	Look–alike /Sound-alike
NCC MERP	National Coordinating Council for Medication Error Reporting and Prevention.
Qualifiers	A word, phrase or letter string that is used to help further define a trade name.
SFDA	Saudi Food & Drug Authority
SPC	Summary of Product Characteristics
Upstrokes	A stroke normally made in an upward direction

1. INTRODUCTION

1.1 Objective

The Drug Sector in Saudi Food & Drug Authority (SFDA) has developed this document to provide guidance for companies on the factors that need to be considered when selecting an invented medicinal product name to reduce medication errors.

1.2 Background

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". This guidance is directed to applicant who are submitting a new proprietary name for a medicinal product, or applying applications for renewal or name variation. This guidance will help the applicant in the process of medicinal product naming to avoid any issues that may lead to occurrence of medication error.

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.

1.3 Scope

The scope of this guideline is to provide applicants with guidance on the criteria applied when reviewing the invented names for medicinal products intended for human use.

1.4 Related Guidelines

This document should be read in conjunction with the following drug sector documents:

- The GCC Data Requirements for Human Drugs Submission
- Guidelines for Variation Requirements

2. SAFETY CONCERNS AND CONFUSION WITH OTHER MEDICINAL PRODUCTS

The SFDA assesses each invented name to minimize the risk of confusion with the name of another medicinal product. Obtaining a trademark for the proposed invented name is not considered justification for accepting a proposed invented name.

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 international non-proprietary names (INN). When assessing the potential for such confusion between two names the following criteria present in table 1 should be considered:

Table1: Criteria Used to Identify Product Names that Look or Sound Similar to a Proposed Invented Name

Type of similarity	Potential causes of product name similarity	Attributes examined to identify similar product names	Potential Effects
Look-alike	Similar spelling	- Identical prefix - Identical infix - Identical suffix - Length of the name	- Names may appear similar in print or electronic media and lead to product name confusion in printed or electronic communication - Names may look similar when scripted and lead to product's name confusion in written communication.
	Orthographic similarity	- Similar spelling Length of the name - Upstrokes (e.g., h, l) - Down strokes (e.g., p, q) - Cross-strokes (e.g., t) - Dotted letters (e.g., i) - Ambiguity introduced by scripting letters (many letters look similar when scripted)	Names may look similar when scripted, and lead to product name confusion in written communication
Sound-alike	Phonological similarity	- Identical prefix - Identical infix - Identical suffix - Same number of syllables - Stresses - Placement of vowel sounds - Placement of consonant sounds	Names may sound similar when pronounced and lead to product name confusion in spoken communication.

In addition to similarity of the names, similarity in the product characteristics between two products may increase the risk of confusion and should be systematically assessed by applicant. These product characteristics include:

- Indication(s).
- Patient population(s).
- Prescriber (e.g., specialist).
- Dosage form(s).
- Dose.
- Dosage units.
- Route(s) of administration.
- Dosage strength(s).
- Storage conditions.
- Contraindication.
- Clinical setting for dispensing and use (e.g., restricted to hospital setting).

The applicant should also assess the risk of harm (e.g. high alert medications). The Applicant should check the Institute for Safe Medication Practices (ISMP) "List of High-Alert Medications in Acute Care Settings[5]" website to determine which drugs fall under the high alert category.

Obvious Similarities in Spelling and Pronunciation of Proprietary Names:

Generally, proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other registered products at SFDA.

Inert or Inactive Ingredients:

Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that creates an impression that the ingredient's value is greater than its true functional role in the formulation.

3. USE OF INTERNATIONAL NON-PROPRIETARY NAMES (INN)

The Applicant is expected to review INN use before requesting that the proposed invented name(s) be considered.

The invented name should not incorporate an exact INN stem in the stem position for that drug. This is in accordance with World Health Assembly Resolution (WHA) 46.19, which states that an invented name should not be derived from its own INN.

Additionally, use of an INN that designates a different drug class should also be avoided, as it may be misleading (e.g., practitioners may think the drug is from another pharmacologic class).

By including the same INN stem in the invented name as the INN, healthcare professionals could consider that this is a new active substance as opposed to an invented name; by including a different INN stem healthcare professional could consider that this is a different class of medication rather than an invented name.

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.

A full list of INN stems is available on the WHO website:
https://www.who.int/medicines/services/inn/stembook/en/

United States Adopted Name (USAN) Stems

USAN stems are intended to indicate a pharmacological or chemical trait of a drug, and a single stem may be applicable to multiple drug products.

Proprietary names should not incorporate USAN stems in the position that USAN designates for the stem (e.g., Drugostatin) as this can result in the creation of multiple similar proprietary names and/or proprietary names that are similar to established names.

According to the WHO and USAN, the well- established stem should not be used in or as trade-marks.

4. ASSESSING THE SUITABILITY OF INVENTED NAMES FOR USE IN MEDICINAL PRODUCTS

The applicant should submit one proposed (invented) name for each medicinal product. Drug sector will review the name and if it is not acceptable, the company will be asked to provide another name.

General Principles

The applicant should use the principles below to aid in the development of the invented name:

1. The invented name should not be liable to confusion with the generic or the invented name of any other medicinal product.
2. The invented name should not be liable to confusion with other names of products, which were withdrawn from the market.
3. The invented name should not be misleading with respect to promotional issues and make claims relevant to:
    - Overstatement of product efficacy,
    - Minimization of risk,
    - Broadening of product indication,
    - Unsubstantiated superiority claims, or
    - Being overly fanciful.
4. 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)
5. 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.
6. If the invented name includes the name of an ingredient which is not contained in the medicinal product, it will be considered misleading.

7. 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.

5. ASSESSING THE SUITABILITY OF INVENTED NAMES FOR NON-PRESCRIPTION MEDICINES

The following terms which form part of the invented name will only be considered where the specified conditions are met by the applicant. Derivatives of the listed terms with regards to spelling and other connotations, if misleading, will not be approved:

- **Fast acting, Express:** (including derivatives such as Xpress) and any other terms indicating a 'quick' or 'fast' onset of action should only be used where this claim is supported by data in the SPC and is relevant to the indication(s) for which the product is being marketed (e.g., onset of action in < 30 minutes from oral administration);
- **Once-a-day:** should only be used where a unit dose is taken or administered once in a day. Half-a-tablet twice a day, with the justification that the total dose per day is equivalent to one tablet is not acceptable. Once-a day may be used where one or more tablets are taken or administered once a day;
- **PLUS, Extra:** (including derivatives such as Xtra) should only be used where the medicinal product contains an additional active ingredient which confers a synergistic or additional therapeutic action or benefit;
- **Triple action:** should only be used where the medicinal product clearly has three different therapeutic actions. This may be a product with a single active substance with three different actions or three active ingredients with different modes of action. Where the claim has a qualified therapeutic action, (e.g., 'Triple action pain relief'), the three different actions must be relevant to pain relief;
- **Advance:** should only be used when it can be demonstrated that enhancement has been achieved with the new product compared with the existing product. This may be an enhancement in a therapeutic action or enhancement resulting from a formulation change. The addition of increased amounts of the active ingredient and/or excipient(s) without evidence of enhanced therapeutic benefit is not acceptable justification; similarly, minor

changes in formulation that do not provide recognizable benefits over the existing product do not constitute enhancement;

- **Maximum strength:** should only be used where there are different strengths of products containing the same ingredient and the strength is the maximum available;
- **Flavors:** have to be identified as such, (e.g. the term 'strawberry' in a name is acceptable if there is fruit or natural extract contained in the product; if present as an artificial flavoring will have to be listed as 'strawberry flavor' in the product name).

6. ASSESSING THE SUITABILITY OF QUALIFIERS /ABBREVIATIONS

Applicant should provide justification to the SFDA when requesting a qualifier.

6.1. Composition of the Qualifier

The use of qualifiers/abbreviations by letters as part of the invented name is, in principle, acceptable. 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.

6.2. Selection of a Qualifier or Abbreviation

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.

6.3. Prolonged-release Preparations

Applicants are advised that the following suffixes should be used for prolonged release preparations, as appropriate to the particular product:

- CR – Controlled release.
- LA – Long acting.
- PR – Prolonged release.
- SA – Sustained action.
- SR – Sustained release.
- XR – Extended release.
- XL – Prolonged release, once daily dosing. If a product can be given once or twice daily, a different suffix should be used.

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.

6.4. Gastro-resistant Preparations

Applicants are advised that the following suffixes should be used for gastro- resistant preparations, as appropriate to the particular product:

- EC – Enteric coated.
- GR – Gastro resistant.

Incorporation of Company's Name

- Proprietary names should not incorporate the company's name, or some part of the company's name across multiple products. This practice results in creating multiple similar proprietary names, increasing the risk of confusion across products.
- If the company submits a generic name plus either an abbreviation of a company or full name after the name (not attached to the name), this will be accepted, for example: Cepecitabine SFDA.
- 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, for example: CefaSFDA

- If the company presented the following: brand name-company name, for example: Moxavel SFDA. The name will be rejected and the company has two options:

  -Either delete the company name, for example: Moxavel.

  -or replace the brand name with the generic name, for example: MoxifloxacinSFDA.

- If the company submits a generic name plus either an abbreviation of a company or full name on the beginning, this will be rejected, for example: SFDA Atenolol.
- If the company submits part or full generic name without the name of the company.
- If part of the generic name without the INN stem included (depends on the case). This may lead to cutting the brand name, which may expose us to a new INN stem, or be similar to a certain other therapeutic class.
- If the complete generic name is presented without the company's name, we can accept it.

BIOLOGICAL PRODUCT

Regarding biological medicinal products, the same criteria apply as for any other medicinal products in respect to the (invented) name.

7. FACTORS TO BE ADDRESSED IN APPLICATIONS

It is highly recommended in order to facilitate SFDA's consideration of the assessment of proposed product name; applicants should consider and address the type of factors listed below in their application. A risk analysis for the new application, taking into account all of these points, and considering the impact on existing products would facilitate SFDA consideration. Applicants should address how they propose to deal with any potential risks identified or explain why, in their opinion; the identified risks would not present a problem.

The applicant should examine and include information in its application using the following criteria:

- Description of other products within the company's own range. The company should review the new invented name and compare it with other companies' products names for LA/SA similarity.
- The company should assess the invented product name for LA/SA potential with all other drugs registered in Saudi Arabia (registered drug list is available at SFDA's website or per request).
- Derivation of names (how did the company choose the name and is there any meaning of the name).
- Invented meaning of name and modifier (definitions of symbols or abbreviations if it is included in the name).
- Use of different suffixes/prefixes etc.
- Therapeutic class of drug.
- The Invented name should not contain number
- Care environment for dispensing and use (area in which the drug is utilized).
- Delivery system and measuring device (if the product needs a device for use, the company should address the device used and how it measures).
- Indication(s).

- Patient population(s).
- Prescriber.
- Dosage form(s).
- Dosage units.
- Frequency.
- The route(s) of administration.
- Dosage strength(s).
- Storage conditions.
- Contraindication.
- Any special consideration regarding the drug product (e.g. for IV use only).
- Harm (e.g. high alert medications which are drugs that bear a heightened risk of causing significant patient harm when they are used in error).

In the case of a product name variation (Refer to The Guidelines for Variation Requirements), the company needs to provide justification(s) for this change and do above mentioned assessment steps.

If the proposed name is rejected, the company is committed to submit updated file with the new name after fulfilling all registration requirements.

Approval of a name by the SFDA does not relieve the applicant of its responsibility should actual or potential hazards come to light following marketing of the product. In these circumstances, the SFDA must be advised and appropriate action taken.

REFERENCES

1- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

2- PDUFA Pilot Project Proprietary Name Review – Concept paper, September 2008. Available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

3- Guideline on the acceptability of names for human medicinal products processed through the centralized procedure, EMA/CHMP/287710/2014-Rev. 6

4- MHRA Guideline for the naming of Medicinal products and Braille requirements for name on label, May 2009.

5- National Coordinating Council for Medication Error Reporting and Prevention.

6- Institute for Safe Medication Practices (ISMP), List of High- Alert Medications in Acute Care Settings.