LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

# Guideline for naming medicinal products

Version: 2

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# Content

# Introduction

This guideline is intended to increase the understanding of the Swedish Medical Products Agency's assessment of product names in accordance with the Medical Products Agency's provisions (LVFS 2005:11) on labelling and package leaflets for medicinal products, the Medical Products Agency's provisions (LVFS 2012:19) on parallel imported medicinal products, the Medical Products Agency's provisions (HSLF-FS 2017:75) on homeopathic medicinal products and the Medical Products Agency's provisions (LVFS 2006:3) on traditional herbal medicinal products for human use in regard to the naming of products. The guideline has been produced to support the companies naming medicinal products. It is based on the Guideline on the acceptability of names for human medicinal products processed through the centralised procedure[1] used by the EMA.

The guideline describes the Medical Products Agency's interpretation of the contents of applicable provisions. A guideline may contain additional information compared to the provisions, with the aim of increasing the understanding of the requirements set out in the code of statutes. The guideline is not legally binding, but it comprises examples and recommendations that may be of help in the assessment and implementation of the statute provisions. The guideline does not exclude other means of achieving the results intended in the provisions, but rather represents the interpretation of the Medical Products Agency.

This guideline should be read as a complement to the Medical Products Agency's provisions (LVFS 2005:11) on labelling and package leaflets for medicinal products, the Medical Products Agency's provisions (LVFS 2012:19) on parallel imported medicinal products, the Medical Products Agency's provisions (HSLF-FS 2017:75) on homeopathic medicinal products and the Medical Products Agency's provisions (LVFS 2006:3) on traditional herbal medicinal products for human use which specify applicable requirements.

The guideline concerns names submitted in new applications within a national, mutual recognition or decentralised procedure, and in variation applications regarding name changes in national and mutual recognition procedures. For centralised procedure applications, please refer to the EMA guideline.

### Definitions

Name, strength and pharmaceutical form must always be considered as a unit when identifying a medicinal product. The name alone can never be used to identify a medicinal product.

The name of the medicinal product is simply the product name and can either be an invented name or a generic name.

### Background

The Medical Products Agency is to review and approve submitted names in new applications as well as name changes for already approved or registered medicinal products.

Chapter 4, Section 1 of the Medicinal Products Act (2015:315) states, among other things, that a medicinal product must have an acceptable and distinctive designation. Both invented names and generic names can be used in the naming of medicinal products. The considerations below must be made when proposals for invented or generic names are

[1] https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure_en.pdf

submitted to the Medical Products Agency. The Medical Products Agency makes an overall assessment of the factors described below before making a decision on whether the suggested name is acceptable.

## 1. The following is taken into consideration when a proposal for an invented name is submitted to the Medical Products Agency (Section 1, LVFS 2005:11)

The fundamental criterion is that the invented name must not constitute a risk to public health.

a) The name may not indicate any misleading therapeutic or pharmaceutical properties.
b) The name may not be misleading in terms of the product composition.
c) It must not be possible for the name to be confused in print, handwriting or pronunciation with the name of an existing or recently deregistered medicinal product.
d) The name must not be of a marketing nature, nor be perceived as offensive or have an inappropriate meaning.
e) The name should preferably consist of a single word.
f) The name must not consist of a proper noun or words with a well-established meaning.
g) The name cannot be the same as the company name. Nor should a company name constitute the beginning of the name of a medicinal product. The full company name should not be included in the name of the medicinal product.
h) Suffixes should only be used exceptionally, for example if there is a need to distinguish between products containing the same active substance but where one product contains another substance as well. Suffixes in the form of numbers alone must be avoided to reduce the risk of being confused with the strength. Double suffixes will normally not be accepted.
i) Only abbreviations and suffixes that have an established and relevant meaning will normally be accepted, and should then to the greatest extent possible be in Swedish.
j) The first letter of the name should be capitalised. Capital letters and other distinctive symbols, such as dashes and hyphens, should otherwise be avoided.
k) At least two letters should distinguish a new proposed product name from an already approved or accepted product name.
l) For medicinal products containing a prodrug, i.e. a pharmacologically inactive compound that has to be converted to an active drug in the body before it can produce a pharmacologic effect, a different name from the invented name of the medicinal product containing the related active substance is required.
m) Medical gases should not have invented names as they are often used in acute/lifethreatening situations and should therefore have generic names to enable quick identification.
n) Medicinal products should not have the same name as products of other classifications, such as medical devices or foodstuffs.

If the Medical Products Agency finds that there is a risk of confusion between the suggested name and an existing name, other distinguishing factors can be considered in the assessment. Such factors include the following:

- Pharmaceutical form
- Route of administration
- Indication and condition of supply
- Patient group

- The degree of similarity between names weighed against the risk of harm to a patient in the event of confusion

The Medical Products Agency recommends adding the suffix "Vet" to veterinary medicinal products. Proposed names for veterinary medicinal products that are considered too similar to a name of a human medicinal product can be acceptable in some cases, provided that the suffix "Vet" is added.

A special assessment is carried out in cases where the Medical Products Agency considers there to be a risk of a proposed name being confused with the name of a deregistered product. At least five years should pass from the deregistration before the same or a similar name can be used for a different product. A shorter period may be acceptable in some cases.

The name should also adhere to the WHO naming guidelines[2]. The WHO recommends, for example, that invented names should not be derived from INNs (International Nonproprietary Names, i.e. the international generic name recommended by the WHO) and should not contain INN stems, in order to avoid confusion between different drugs and to avoid making the establishment of new INNs more difficult.

## 2. The following is taken into consideration when a proposal for an invented name is submitted to the Medical Products Agency (Sections 1 and 1 a of LVFS 2005:11)

a) Generic names of medicinal products shall consist of the substance INN, or, if no such name is available, the European Pharmacopoeia name. In both instances, the substance name shall be followed by the name, or a trademark, of the marketing authorisation holder (MAH).
b) If the MAH does not have a permanent operation in Sweden, the name or trademark of their local representative may be used instead. The trademark must be registered for sales by the MAH with the Swedish Patent and Registration Office (PRV) or the European Union Intellectual Property Office (EUIPO).
c) A trademark that is considered promotional, contains numbers or in other ways is considered to be misleading (see section 1a and 1b) is not suitable as part of the name of a medicinal product.
d) Generic names can be used in cases where the medicinal product contains up to three different active substances. The active substance shall be indicated in either Swedish or English. If the Swedish name differs significantly from the English one, as in the case of potassium chloride (*kaliumklorid*), the name is to be given in Swedish. For herbal medicinal products and traditional medicinal products, see section 3.
e) The basic principle is that the salt must not be included in generic names as it makes the names unnecessarily long and complex, and the salt usually has no pharmacological effect. This applies whether the concentration refers to the salt or to the acid/base (parent compound). However, in some cases, the salt must be specified in order to avoid misunderstandings, for example if there is a different salt previously approved with a generic name where the strength is based on the salt. Consistent naming is strived for when it comes to medicinal products with generic names that contain the same substance and salt.

[2] http://apps.who.int/iris/bitstream/10665/68742/1/WHO_EDM_QSM_2004.5.pdf

f) The basic principle is that an ester/ether will only be indicated in generic names if this is the form that has a pharmacological effect. Otherwise, the hydrolysed ester/ether (parent compound) is indicated.
g) In the case of generic naming, no suffix should be added.
h) It is important to establish whether a generic name sufficiently distinguishes the medicinal product from other medicinal products, or if there are differences which are not captured by the generic name. An example of such a difference could be if one pharmaceutical form is used for compounds with different properties, e.g. *solution for injection*, which may be used for liposome preparations as well as solutions.

## 3. The following principles are considered when names are submitted to the Medical Products Agency for herbal medicinal products and traditional herbal medicinal products.

- The same principles as are described in section 1 for invented names are also applied to herbal medicinal products and traditional herbal medicinal products.
- The corresponding principles as described in section 2 in regard to generic names are also applied to herbal medicinal products and traditional herbal medicinal products; however, the substance name consists of the name of the active plant used. The Latin, Swedish or English name of the plant is acceptable.
  In some cases, the name of the family can be acceptable as a generic name, such as Echinacea, Valeriana or Ginkgo. This is applicable in cases where different species can be considered interchangeable in terms of effect/safety or when the species referred to is commonly known. Certain species epithets can also be acceptable generic names, as in ginseng. Family name along with species epithet can also be an acceptable generic name, such as Hedera helix.
  The plant part or type of preparation should not be included in the name.

## 4. The following principles shall be considered when submitting names for parallel imported medicinal products to the Medical Products Agency (Section 14 of the Medical Products Agency's provisions (LVFS 2012:19) on parallel imported medicinal products)

Naming of parallel imported medicinal products is subject to the same general naming principles as specified in sections 1 and 2 in regard to invented and generic names, with the following additions.

- In most cases, the name of the direct imported medicinal product can be used by the parallel importer. Exceptions may occur as it is not permitted to name a parallel imported medicinal product using an INN followed by the name of a MAH or local representative, which would be misleading in this context.

- If the parallel importer is bringing in medicinal products from different countries, the INN followed by the name of the parallel importer may only be used for several of these products if they refer to the same direct import to Sweden.
- For a parallel imported medicinal product, the invented name from the exit country may be used as long as it is not already being used for a medicinal product approved in Sweden through another procedure, and does not violate the general principles described in sections 1 and 2.
- If the direct imported medicinal product has a suffix in its invented name, the parallel import medicinal product must have the same suffix. In cases where the parallel importer chooses to use an INN when the corresponding direct imported medicinal product has an invented name with a suffix, the INN must normally not contain a suffix.

## 5. The following is taken into consideration when a proposal for an invented name is submitted to the Medical Products Agency (Chapter 3, Section 1 of the Medical Products Agency's provisions (HSLF-FS 2017:75) on homeopathic medicinal products)

- For a single agent (containing a homeopathic stock), the name of the product should preferably consist of the name of the corresponding monograph in the European Pharmacopoeia or in another homeopathic pharmacopoeia used officially within the EEA.
- For compound agents (containing two or more stock preparations), including potency chords (containing several dilutions of the same stock preparation), invented names may be used. The invented name must not allude to any pharmacological effect or therapeutic indication. Otherwise, the same principles for invented names as described in section 1 are applicable.

## 6. Review of submitted names

**New applications:**
The Medical Products Agency reviews the submitted names for all new applications in national, decentralised and mutual recognition procedures.
A submitted name will only be approved in conjunction with the medicinal product being approved or registered in Sweden.

**Name changes for already approved or registered medicinal products:**
Requests for name changes for an already approved or registered medicinal product must be made in the form of a variation application.
All names submitted in national and mutual recognition procedures will be reviewed. In cases where the procedure results in a new acceptable name, the Medical Products Agency and the applicant must agree on a time for implementation of the new name. The implementation date can be postponed for a maximum of one year after the matter is closed.
In conjunction with the implementation, the Medical Products Agency will update its database and update and publish the product information under the new name. Packaging with the old and the new name may only be available in parallel for one month following the agreed implementation date.

The MAH change must be completed before a name change to a generic name + new MAH can be made.

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