

Guideline on names of medicinal products

The guideline on names of medicinal products has been developed amongst other on the request of the pharmaceutical industry, to be put into practice until the above mentioned provisions and guidelines has been changed.

The following different types of names can be used on medicinal products:

1. Invented name
2. INN (the International Nonproprietary Name recommended by the World Health Organization) or if one does not exist the European Pharmacopoeia name, followed by a trademark or the name of the marketing authorization holder. Unless the marketing authorization holder does not have a permanent establishment in Sweden a trade mark or the name of, the local representative can be used instead.

Guideline on invented names of medicinal products¹:

The paramount criterion is risk for the public health.

The invented name of a medicinal product should not:

- convey misleading therapeutic or pharmaceutical connotations
- be misleading with respect to the composition of the product
- be liable to cause confusion in print, handwriting or speech with the invented name of an existing medicinal product.

If there is a risk of confusion in print, handwriting or speech with the invented name of an existing medicinal product, other distinguishing factors are taken into account such as:

- The pharmaceutical form
- The route of administration
- The indication and condition of supply
- Potential new pharmaceutical forms and/or routes of administration for the medicinal product concerned as well as for the other medicinal products with a similar invented name.

The following principles are applied to reach consensus amongst the member states of the European Union:

- The invented name should preferably consist of only one word. It should therefore avoid qualification by letters or numbers. The use of short qualifications/abbreviations which do not carry an established and relevant meaning is unacceptable. Promotional qualifications/abbreviations/manufacturers codes are also unacceptable. The use of descriptive abbreviations could be acceptable if there is a need to distinguish different routes of administration for the same medicinal product.
- The invented name should not convey any promotional message with respect to the use of the medicinal product.

¹ The guideline is based on the guideline of EMEA, on the acceptability of invented names for human medicinal products processed through the centralised procedure. The guideline of EMEA is found at <http://www.emea.europa.eu/pdfs/human/regaffair/032898en.pdf>

- Use of capitals and other characteristic letters in invented names should reflect the proposed/approved trademark registration.
- 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.

After assessing the above-mentioned factors as a whole, the Medical Products Agency will decide if the proposed name of a medicinal product creates a risk for the public health.

Concerns which are expressed by the WHO ought to be taken into account.² The WHO recommends that invented names are not derived from INNs and that INN stems are not used in invented names, to avoid confusion between different medicinal products and to not frustrate the rational selection of further INNs.

Guideline revised 2009-12-15

² Document WHO/EDM/QSM/99.6 which can be requested from the WHO.