REG-29 version 2 NAMES OF MEDICINAL PRODUCTS

This guideline supersedes guideline REG-29, version 1, as of September 01 2010

The assessment of safety of a medicinal product within the scope of marketing authorisation procedure includes also the assessment of acceptability of the name of the medicinal product, particularly with a view to its liability to possible confusion with another product. The name is assessed in complexity, as presented in the application for marketing authorisation or for a change of the name of the product. Each name is assessed individually.

This guideline provides recommendations for the formation of the name and rules applied in the assessment of names, which should be considered also during name formation. These recommendations reflect, in addition to Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended (hereinafter referred to as the "Act on Pharmaceuticals"), also European Directive 2001/83/EC, as amended[1]) and the "Guideline on the acceptability of names for human medicinal products processed through the centralised procedure" CPMP/328/98 published by the European Medicines Agency (EMA) (effective version no. 5)[2]), amended by EMA guideline "Composition of the complete name of medicinal product"[3]). Furthermore, this guideline reflects recommendations of the World Health Organisation (WHO) (WHA 46.19) and WHO materials containing information on international non-proprietary names (INN) and their stems, their formation and method of use[4]).

Pursuant to Section 4, paragraph 1 of the Act on Pharmaceuticals, the name of a medicinal product shall mean the name which may be either an invented name which cannot be confused with a common name, or a common scientific name accompanied by the name or brand identifying the marketing authorisation holder. A common name shall mean an international non-proprietary name recommended by the World Health Organisation, or, where no such international non-proprietary name exists, a commonly used name.

One of the preconditions necessary for the State Institute for Drug Control (hereinafter referred to as the "Institute") to be able to issue marketing authorisation or its decision regarding a variation to marketing authorisation concerning a change of name, is the fact that "**the name of the medicinal product is consistent with its composition and therapeutic effects and may not be confused with the name of another medicinal product which has already been authorised pursuant to Section 25, paragraph 1 or whose application for marketing authorisation is pending with the Institute and has not been legally rejected or which should be, in accordance with the intention notified to the Agency, the subject-matter of an application for marketing authorisation via a Community procedure** " (Section 31, paragraph 5, item 4a) of the Act on Pharmaceuticals). In the assessment of possible confusion it is particularly taken into account whether the name might be confused with the name of another product in its printed, written or pronounced form. At the same time, the likelihood of confusion in common handling of the product and the consequences of such confusion for the health of patients shall be taken into account.

Rules governing the formation and assessment of the name

The name must not:

- Allow for possible confusion with the printed, written or pronounced form of the name of another medicinal product.
  Another medicinal product shall mean a product which has been previously authorised or a product the application for marketing authorisation of which is currently pending and has not been legally rejected. A previously authorised product shall mean also a product with an implemented variation to marketing authorisation, which may be used until its expiry date (such product is flagged with a "B" in SÚKL's List of Authorised Medicinal Products). The names of products the marketing authorisation of which has been suspended or has expired shall be also considered. Names approved by the EMA Name Review Group (NRG) for centralised products shall be considered as well as those of medicinal products under marketing authorisation procedures pending in the Institute. To be more specific, the above mentioned implies that it is not possible to use the name for products with various qualitative compositions of active substances and that

[1]) It is recommended to reflect European regulations also in the formation of names of nationally authorised products.
[2]) http://www.ema.europa.eu/pdfs/human/regaffair/032898en.pdf
[3]) http://www.ema.europa.eu/htms/human/presub/q05.htm
[4]) WHO in general: http://www.who.int/en/
Information on INN: http://www.who.int/medicines/services/inn/innquidance/en/index.html
http://www.who.int/medicines/services/inn/GeneralprinciplesEn.pdf
Information on INN stems: http://whqlibdoc.who.int/hq/2004/WHO_EDM_QSM_2004.5.pdf
http://www.who.int/medicines/services/inn/GeneralprinciplesEn.pdf.

the proposed name of a newly authorised product must not be identical or as similar as the name of a previously authorised product of another holder to cause possible confusion;

- Allow for possible confusion with the common name of an active substance (not applicable to the use of an unchanged common name of the active substance in so called common name of a product containing solely this particular active substance);

- Be misleading or deceptive in respect of the nature of the product – i.e. it must not allow for possibly mistaken interpretation, be inconsistent with the composition, therapeutic effects, indications, pharmaceutical and other properties of the product;

- Be unacceptable linguistically and socially;

- Be of advertising nature.

Furthermore:

- Pursuant to the resolution of the World Health Organisation (WHA 46.19), the invented name should be derived from the INN or, where applicable, from the common name of the active substance, or contain approved INN stems. INN stems shall mean prefixes, suffixes or middle parts of names dedicated by WHO for certain groups of substances published in "The use of common stems in the selection of International Nonproprietary Names (INN) for pharmaceutical substances". This WHO requirement has been, apart from other, invoked by the need to form and systematically structure new INNs for new active substances and by the accompanying problems in blocking the possible name of the substance with a trade name of an authorised medicinal product. This is why it is necessary to take into account the WHO requirement when forming the invented name.
  Where INN stems are used in the name of the medicinal product, or in the case of names derived from an INN or, where applicable, from the common name of the active substance, the following is considered: whether the product belongs to the same therapeutic group and whether wrong interpretation of the name of the product in respect of its composition could occur. The pharmaceutical form, method of administration or method of dispensing and use of the product are also considered (an OTC product, prescription only product, a product the use of which is restricted to specialists or specialised workplaces only, etc.), as well as the fact whether such name could be also the name of a new active substance.

- An invented name should be indeed invented, i.e. it should not be a content word, commonly used name, etc.

- Where a name is considered as not liable to confusion for a certain pharmaceutical form it does not mean that it will be automatically acceptable for another pharmaceutical form, as another pharmaceutical form may, in terms of practical application, have different parameters of liability to confusion.

- A product containing a pro-form or a metabolite of a certain active substance must bear a name different from a product containing this active substance.

- Where the name is based upon a common name, it has to be, for accurate identification purposes, always followed by an identifier specifying the applicant/holder (a brand or corporate name corresponding to the official name of the holder). It should have at least three characters. The use of numericals and symbols other than Latin characters for the identifier distinguishing the products with common names from products of other companies is not acceptable, due to the rapidly increasing number of medicinal products with various parameters. Each marketing authorisation holder should have a single identifier, in order not to complicate orientation in products placed on the market and potential adverse reaction reporting.

Names of medicinal products should not be the same as those of dietary supplements and cosmetic products, including cases of so called "umbrella names" (see below), as medicinal products, their control, method of manufacture and documentation are subjected to more tight requirements than those applicable to other products.

- Where an INN recommended by WHO exists, it should be incorporated in the common name of the medicinal product in the form published by WHO (e.g. without the use of abbreviations). Where no INN exists, a common name may be used. In the Czech Republic, linguistic versions comprehensible to the Czech consumer are acceptable (i.e. particularly Czech and English common names; in the case of homeopathic products the Latin version may also be used).

- Pursuant to Directive 2001/83/EC, as amended by Directive 2004/27/EC, the strength must always form part of the name of a medicinal product. The information about strength shall be stated before the pharmaceutical form. Where the name of the product is based on an invented name, the strength may be expressed numerically, or, particularly in the case of multi-component products, verbally (e.g. for children, for adults, etc.).

The verbal expression of the strength must be consistent with information provided in the SPC or with the expression of strength in other products with the same invented name. In the case of a product name based upon a common name the strength may be expressed only numerically. The numerical statement of the strength must be accompanied by units. The method of numerical specification of the strength must be consistent with the statement of strength in previously authorised products containing the same active substance(s). In the case of substances newly authorised in the Czech Republic, the statement of strength must be compliant with the standards applied in the EU.

- In compliance with the requirements stipulated by Directive 2001/83/EC, as amended by Directive 2004/27/EC, the statement of pharmaceutical form in the SPC, package leaflet and on the outer packaging shall follow immediately after the product name, even if it is intended to be available in a single pharmaceutical form. Where the product has several pharmaceutical forms, its statement shall form an integral part of the product name. The statement of the pharmaceutical form shall be marked, so that it cannot be overlooked, and shall comply with standard terms (please refer to the effective version of the Institute's guideline UST-17). Pursuant to the EMEA guideline "Composition of the complete name of medicinal product"[3]) the strength and pharmaceutical forms should be incorporated in the name in the following order: <name><strength><pharmaceutical form>.

- The use of non-standard/misleading attributes, prefixes and suffixes as well as of data which are not necessary for the qualification of the product shall not be considered acceptable (superlatives, ambiguous expressions, abbreviations, unsubstantiated indications, etc.). It is recommended not to use single-character qualifiers to distinguish various medicinal products. The use of attributes, prefixes or suffixes shall be possible only if a product which does not contain the attribute (prefix, suffix) in its name is authorised.

- Non-specific names of medicinal products (such as common names of pharmaceutical forms, e.g. "Nasal drops") shall be considered unacceptable.

- Distinction between names solely by the statement of the pharmaceuticals form in the case of names of products with different contents of active substances, which are otherwise liable to confusion is not sufficient (this hall not apply in the case of marketing authorisation extended by another pharmaceutical form for a previously authorised product with the same active substance/s).

- In any of the Czech texts which are presented for approval, the symbol ® or ^{TM} may not accompany the name of the product. The statement of these symbols after a trademark is completely the responsibility of the applicant, SÚKL shall not verify their eligibility, and for this reason they shall not be stated in the approved texts of the SPC, package leaflet, on the labelling or in the Institute's decisions. Industrial property protection rights shall not be assessed as part of the marketing authorisation procedure. The holder may add these symbols to the approved texts thereafter.

- An invented name must not be composed of individual letters or individual numericals and it should be longer than a three-character word.

- Symbols such as +, -, =, #,*, & shall not be acceptable as part of the invented name of a medicinal product or for the distinction between products names.

- When assessing the acceptability of the name, upper and lower case shall not be distinguished.

- Homeopathic products shall be subjected to the rules to the extent adequate to their nature. Instead of INN, the name commonly established in homeopathic practice may be also used (preferred pharmacopoeial terms in the German or French pharmacopoeia, such as kalium muriaticum), if followed by the relevant INN or common name of the substance of which the product is manufactured in the package leaflet and on the labelling.

- Names for fixed combination of substances must be sufficiently distinguished from the names of products containing only one active substance.

- Where a new serotype is added to vaccines containing several serotypes, this fact should be reflected in the name. The product name should be followed by the number of serotypes the description of which is specified in the product composition (e.g. "Invented name" X serotypes…). The same process shall be employed when giving names to vaccines containing various types of antigens, where a new type of antigen is added.

- Where a change to the manufacturing process of a biological product occurs (such as line extension), which results in a new version of the product, it shall be possible to keep the old name (the circumstances of the

case have to be assessed). Where, however, the properties of the product change (e.g. by adding a new adjuvant) a new name may be required.

- Pursuant to SÚKL guideline REG-81 the names of medicinal gases should contain the word "medicinal" (e.g. Medicinal oxygen, liquid, "company"). For invented names of such products it shall suffice if such name in the SPC, package leaflet and on the labelling is followed by the standard formulation for the pharmaceutical form:
  Medicinal gas, compressed
  Medicinal gas, cryogenic
  Medicinal gas, liquefied

- In terms of names, radiopharmaceuticals are considered a special product group, particularly due to the different method of handling. A name of a radiopharmaceutical cannot contain the name or symbol of the isotope, unless it is contained in the product.

The use of the name of a product with revoked marketing authorisation
The use of a product which may be confused with the name of a product with revoked marketing authorisation or a product recalled from the market shall be possible after the expiry of at least two years over which the product provably has not been marketed, where the products contain various active substances; potential risks implied by possible product confusion shall be always assessed.

The use of a product name which is liable to confusion with the name of a product with revoked marketing authorisation or of a product recalled from the market, where products with identical or very similar active substances, with the same or very similar indications, contraindications, interactions, etc., are concerned, shall be possible. Even in such a case, however, it shall not be possible to use the older name before the previous product stops to be available on the Czech market and before its expiry date after the marketing authorisation revocation. If the product with the older name has never been placed on the market in the Czech Republic, its name may be used immediately also for another active substance. Potential risks implied by possible product confusion shall be always assessed.

"Umbrella Names"
With a view to the potential risk of confusion, umbrella names may be accepted for OTC medicinal products:
1) containing identical main active substance and identical indication;
2) containing closely related active substances with non-risky confusion (in the case of multi-component products);
3) whose composition is supplemented with another substance;

under the following conditions:

Ad 1) The common main active substance(s) shall mean a substance exhibiting an effect which is substantial for the treatment. The umbrella name shall not be approved for the same active substance used in a significantly different indication, as it may imply a risk for the health of patients, particularly in respect of various dosages (e.g. ASA as an analgesic agent and as an anti-aggregation agent).

Ad 2) Closely related active substances shall mean, for the purposes of this guideline, substances with identical or very similar pharmacological properties, falling within the same chemical and/or indication group. In these cases it shall be necessary to consider all of the properties of the related substances, incl. the frequency and severity of contraindications, adverse reactions and posology so that the health of the patient could not be injured even in the case of product confusion (e.g. products containing paracetamol should not have an umbrella name together with products containing non-steroidal anti-rheumatic agents).

Ad 3) Such products may pose, due to the content of several active substances, an increased risk because of the adverse reactions to and contraindications of substances contained therein, and this risk shall be taken into consideration when assessing the name.

An umbrella name must be supplemented with another section of the name which shall provide for adequate distinction among individual products. This name supplement should express the characteristic property which distinguishes the product of the concerned group from others (it is recommended e.g. to specify the name of the added active substances, such as Exemplin with vitamin C, if the product indications remain without change and if the substance is well-known to the general public). Where more than one substance is added to the basic product, it is necessary to state the most risky substance or all of the substances (Exemplin with vitamin C and caffeine). In such a case it is also possible to state sufficiently understandable parts of the names of the active substances (Exemplin C with caffeine).

The supplementary parts of names of products intended for OTC sale must be explicit and understandable for the general public. It is recommended to provide a specification in the Czech language (in another language only if the concerned expression has been generally used on the Czech market). Distinguishing umbrella products with

another active substance or indication solely by the statement of the pharmaceutical form shall be considered unacceptable.

Exceptionally, umbrella names for prescription-only products may be acceptable, if a substance which does not imply the risk of negative consequences for the health of the patient has been added, or if a characteristic property of the product is highlighted in the name. The umbrella name may be used also in the case of an invented name which differs by a short word distinguishing the two medicinal products, of which one is a slight innovation of the other, e.g. a different manufacturing process, the use of another excipient or active substance salt - Exemplin X mg tablets (contains perindopril erbumine) as well as Exemplin Neo X mg tablets (contains perindopril arginine).
In these cases the consequences for the health of the patient shall be also assessed individually with a view to the nature of the product.

Assessment of names for products authorised via the centralised procedure
These names shall be assessed within the scope of cooperation with the EMA NRG in compliance with the rules stipulated in the "Guideline on the acceptability of names for human medicinal products processed through the Centralised Procedure" (CPMP/328/98).[2])

Preliminary assessment of names of medicinal products
In the case of an application for a preliminary assessment of the name of a medicinal product a written expert opinion may be issued, which shall be subject to reimbursement of costs pursuant to UST-29 (for the current version please refer to the Institute's website, code O-002). This opinion shall be effective only at the moment of its issue, as the proposed name shall be, apart from other, compared to the existing or presented names of medicinal products. The application for preliminary name assessment shall be accompanied by detailed information on the properties of the product, for which the name is being proposed (ideally proposed SPC or PIL) and a proof of payment of the costs. A single application may be filed for a single product only and for the maximum of three proposed names.