REG–29 version 4 Guideline on Assessment of Acceptability of Medicinal Product Names for the Purposes of Marketing Authorisation Procedure

This Guideline supersedes guideline REG-29 version 3 with the effect from January 1 2017.

Contents:

This guideline has been drafted in order to facilitate orientation in the matters of medicinal product names and rules governing the assessment and formation of these names in view of public health protection and patient safety, while concurrently respecting the development of the pharmaceutical industry, as the two principal requirements which create the basis of the current legislation regarding the medicinal products.[1]

1) Legal sources and related regulations

- Directive No 2001/83/EC on the Community code relating to medicinal products for human use, as amended (hereinafter referred to as “Directive 2001/83/EC”)
- Regulation no. 726/2004/EC, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as amended (hereinafter referred to as "Regulation no. 726/2004")
- Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended (hereinafter referred to as “Act on Pharmaceuticals”)
- Decree No 228/2008 Coll., on marketing authorisation of medicinal products, as amended (hereinafter referred to as “Marketing Authorisation Decree“)
- Act No 500/2004 Coll., the Code of Administrative Procedure, as amended (hereinafter referred to as “Administrative Code”)
- Guideline on the acceptability of names for human medicinal products processed through the centralised procedure EMA/CHMP/287710/2014 (hereinafter referred to as “EMA NRG Guideline“)
- Resolution of the World Health Organisation (WHA 46.19) (hereinafter referred to as “WHO Resolution”)
- The use of stems in the selection of International Nonproprietary Names (INN) for pharmaceutical substances (hereinafter referred to as “INN stems”)
- QRD recommendations on the expression of strength in the name of centrally authorised human medicinal products (as stated in section 1 of SmPC, and in the name section of labelling and PL) EMA/707229/2009) (hereinafter referred to as “EMA QRD Recommendation“)
- Guideline on summary of product characteristics (SmPC) Notice to Applicants (hereinafter referred to as “SmPC Guideline”)
- NRG position paper re-use of invented names of medicinal products EMA/648795/2009 (hereinafter referred to as “NRG re-use”)

[1] Cf. items 2 and 3 of the rationale of Directive 2001/83/EC as well as e.g. the ruling of the Supreme Administrative Court of 20 December 2012, ref. no. 4 Ads 9/2012-37: “*…in the opinion of the Supreme Administrative Court, it is necessary to take into account particularly the meaning and purpose of the Act on Pharmaceuticals, which has been harmonised with the regulations of the European Community reflecting globally accepted standards, to safeguard the safety and protection of health of inhabitants and the environment in relation to medicinal products. Furthermore, the Act on Pharmaceuticals strives to improve the availability of medicinal products, to enhance surveillance over their circulation, and prevent incorrect use or misuse of medicinal products. Briefly, the meaning and purpose of the Act on Pharmaceuticals is to contribute to the safeguarding of the best possible healthcare for the inhabitants of the Czech Republic."*

- Guideline on the readability of the labelling and package leaflet of medicinal products for human use (ENTR/F/2/SF/jr (2009)D/869) (hereinafter referred to as “Readability Guideline”)
- European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure (hereinafter referred to as “EMA Pre-authorisation Recommendation“)
- Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products EMA/287539/2005 (hereinafter referred to as “Guideline on herbal products”)
- Guideline on medicinal gases: pharmaceutical documentation CPMP/QWP/1719/00 (hereinafter referred to as “Guideline on medicinal gases”)
- Table X: Standard names of pharmaceutical forms, methods of administration and packaging components, as currently amended – SÚKL guideline based upon "Standard Terms for dosage forms, routes of administration and containers", (ISBN 92-871-5734-0). Coordination is provided by a working group of the European Directorate for the Quality of Medicines (EDQM) (SÚKL's website – http://www.sukl.cz/leciva/standardni-nazvy-lekovych-forem-zpusobu-podani-a-obalu) (hereinafter referred to as “Table X“)
- Compilation of QRD decisions on stylistic matters in product information (EMA/25090/2002) (hereinafter referred to as “EMA stylistic matters”)
- CMDh Questions and Answers Generic Applications (CMDh/272/2012)
- UST-29: Administrative fees, reimbursements of costs of expert activities, reimbursements of activities associated with the provision of information and reimbursements of other activities (code O-002) (hereinafter referred to as “UST-29”)
- Commission Regulation No 1234/2008 (hereinafter referred to as “Commission Regulation““)

2) Medicinal product name – term and general definition

The name of a medicinal product is one of the substantial particulars of an application for marketing authorisation of a medicinal product [cf. Section 26, paragraph 5(a) of the Act on Pharmaceuticals]. Its proper determination is therefore not only an important means of individualisation of the medicinal product, but also one of the prerequisites of successful marketing authorisation. Medicinal product name is defined by **Section 4, paragraph 1** of the Act on Pharmaceuticals as “*… the name, which may be either an invented name that cannot be confused with the common name, or a common or scientific name, together with the name or trade mark of the marketing authorisation holder. …”.* The aforementioned definition is, in terms of its content, identical to the definition provided under Article 1, paragraphs 20 and 21 of Directive 2001/83/EC.

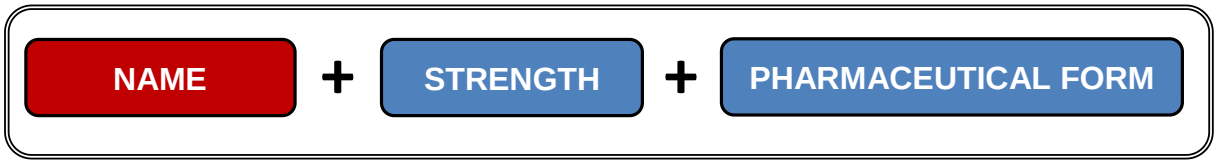
The aforementioned provision of the Act on Pharmaceuticals contains not only the definition of the name, but also basic criteria for its content. In view of this, a medicinal product name may only be:

- An invented name that cannot be confused with a common name; or
- A common or scientific name accompanied by the name or trade mark of the marketing authorisation holder (hereinafter referred to as “MAH”).

While interpreting the term “name”, Section 31, paragraph 5(a) item 4 and Section 37, paragraph 1 of the Act on Pharmaceuticals, as well as Section 6 of the Marketing Authorisation Decree and Annexes 3, 4 and 5 thereto, and the WHO Resolution should be taken into account. Considering the need for adequate harmonisation, guidelines of the European Medicines Agency (EMA NRG Guideline, EMA QRD Recommendation and EMA Pre-authorisation Recommendation) are also taken into account, and although they are not generally legally binding such as official legal regulations, they may be considered part of European “Soft Law”, which (as well as Commission Guidelines) enjoys certain public authority and is taken into account even by the EU Court of Justice when the concepts contained in the EU legislation are being interpreted.[2]
According to **Section 4, paragraph 1** of the Act on Pharmaceuticals the name of a medicinal product may be either an invented name or a common name together with the name or trademark of the MAH. The name of a medicinal product in the product information is followed by the standard expression of strength with units and standard expression of pharmaceutical form (see Table X). The name followed by the expression of strength and pharmaceutical form creates so called “full product name”.

[2] Cf. Ruling of the EU Court of Justice of 20 January 2005: *SmithKline Beecham plc v. Lægemiddelstyrelsen*, no. C–74/03 item 42, rationale (available from www.eur-lex.eu).

Full product name:



While evaluating the possibility of confusion of the proposed product name (either the invented name or the common name) the State Institute for Drug Control (hereinafter referred to as "SÚKL") will always assess the full product name, i.e. the name followed by the expression of strength with units and pharmaceutical form as stated by the applicant in the section 1 of the SmPC. However, for the purpose of marketing authorisation, the applicant provides only the name of the medicinal product (i.e. without the expression of strength and pharmaceutical form) in the application for a marketing authorisation (or in the Annex 5.19).

Invented name

As for the invented names, it is necessary to make sure they do not contain an international non-proprietary name (INN) recommended by the World Health Organisation (hereinafter referred to as "WHO") or its stems (INN stems) reserved by the WHO for a particular group of substances. Furthermore, an invented name should not be derived from the INN because such name could be misinterpreted as the name of a new active substance or a product of a different composition and different therapeutic effects. Failure to comply with this rule set forth by the WHO Resolution could result in disrupting the long used WHO INN structuring system.

With a view to the aforementioned, the invented name of the medicinal product could be only a truly invented (fictitious) name, not a content word or a commonly used name (otherwise the name would not comply not only with the statutory definition of the medicinal product name, but potentially also with the labelling requirements stipulated under Section 37, paragraph 1 of the Act on Pharmaceuticals). Additionally, the invented name must not be offensive or have negative or vulgar connotations, particularly in cases where the invented name is created in a way that it bears a meaning in the Czech language.

The invented name should not be formed as a combination of two content words or a content word with a prefix or suffix, as this would not be an invented name as referred to by Section 4, paragraph 1 of the Act on Pharmaceuticals (it would be a mixture of content words).

Examples:
An invented name of a medicinal product containing paracetamol:

a) Acceptable: Parhau – the name is invented, cannot be confused with the name of another medicinal product or with an INN, it does not contain INN stems, it is not inconsistent with the composition and therapeutic effects of the product, it is not misleading in terms of the target group of patients or in relation to the SmPC, it is not an element of promotional nature
b) Unacceptable:
    i) Containing an INN stem:
    Parazomab – contains an INN stem -MAB reserved by the WHO for monoclonal antibodies
    ii) Derived from/may be confused with a common name of an active substance (hence not compliant with the requirements of the WHO Resolution):
    Paracet – the name was created simply by shortening of the INN paracetamol
    Paracemol – the name was created by simple deletion of one syllable from the INN – and hence may be confused with the common name of the active substance, in this case with the INN paracetamol
    Pacetaramol – the name was created as an anagram of the INN paracetamol
    iii) May be confused with the name of another medicinal product:
    Brusen – the name could be confused with the name of an authorised medicinal product Brufen (containing another active substance – ibuprofen) and there is potential for harm to the patients in case of mix-up
    iv) Misleading with respect to the composition and therapeutic effects of the product:

Valsamol – for a medicinal product containing paracetamol the name is misleading with respect to the composition and therapeutic effects of the product, as it is derived from the INN valsartan, and hence suggests the content of the active substance valsartan

v) Misleading in relation to the target patient group and the Summary of the Product Characteristics:
Parababy – the name is not an invented name, it contains the content word BABY and, moreover, if the product is not intended solely for paediatric population, the name causes confusion in relation to the target patient group and is inconsistent with the data in the SmPC
Paratab – the suffix –tab suggests that the product is available in the form of tablets; for a product available in the form of an oral solution the name is misleading in relation to the target patient group and the Summary of the Product Characteristics

vi) Containing a content word which may be considered an element of promotional nature:
Parsuper – this is not an invented name, it contains the content word SUPER, which may be, moreover, of promotional nature
Prolove – the name is created by a prefix and a content word: PRO + LOVE, hence the name is not invented; in case the medicinal product contained e.g. sildenafil, it would be, moreover, an unacceptable element of promotional nature

Common name

Generally, a "common name" has been defined in Directive 2001/83/EC (Art. 1, paragraph 21) and its definition has been implemented in the Act on Pharmaceuticals (Section 4, paragraph 1, sentence two) as the international non-proprietary name recommended by the WHO or, if one does not exist, the commonly used name.
Where the INN recommended by the WHO exists, it is required that on the basis of the WHO Resolution it is used in the common name of the medicinal product in the same form as published by the WHO on the INN list (e.g. without abbreviations), in order to avoid the risk of misinterpretation of the name or confusion with other medicinal products.[3] Where no INN exists, SÚKL allows that a preferred common name may be used, in the following preferential order:

- Pharmacopoeial name (as per the Czech Pharmacopoeia, European Pharmacopoeia);
- Scientific name, specified as a preferred scientific name in SÚKL's database.

In the Czech Republic, linguistic versions comprehensible for the Czech consumers are acceptable (Czech and English common name; for homeopathic products and some herbal medicinal products also Latin versions may be used).

Where a name based upon a common name is concerned, it shall be always, for the purposes of unique identification, accompanied by an identifier of the marketing authorisation holder (hereinafter referred to as "MAH"), i.e. by the name or brand identifying the MAH. The Act on Pharmaceuticals stipulates that the common name (INN) is accompanied by the name or brand of the MAH. The MAH identifier may hence only follow the common name. In order to insure an easier identification of the medicinal product, and also with a view to the safety of use and prescription, SÚKL recommends that each marketing authorisation holder uses a single identifier in the common names of medicinal products only. In justified cases, however, SÚKL may permit more than one identifier for a single MAH (e.g. where the MAH already has a product authorised under the common name and applies for a new marketing authorisation of a product with identical active substance of identical strength and pharmaceutical form). The aforementioned implies that in case of a transfer of marketing authorisation to a new MAH, SÚKL requires the submission of an application for variation in the common name of the medicinal product (MAH identifier) as, pursuant to the law, the identifier has to identify the marketing authorisation holder (i.e. the current marketing authorisation holder).

Examples:

[3] Cf. Section 31, paragraph 5(a) item 4 of the Act on Pharmaceuticals: *"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 l or whose application for marketing authorisation is pending with SÚKL 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 and, furthermore, whether or not it invokes a deceitful or misleading impression when assessing the name of the medicinal product in relation to the patient target group and summary of the product characteristics"*.

A common name of a medicinal product

a) Acceptable options of the common name
   i) Existing INN:
      Paracetamol MAH
   ii) Non-existent INN, but existing pharmacopoeial name:
      Glucose MAH
   iii) Non-existent INN or pharmacopoeial name, hence the preferred scientific name is to be used:
      Selene MAH

b) Non-acceptable options for the common name:
   i) Paracetamol – INN without MAH identification
   ii) Paracet MAH – abbreviated INN, not a common name
   iii) Paracemol MAH – derived from INN, not a common name
   iv) Paracetamolum MAH – the name of the active substance is in Latin

In the product information, both the invented and the common name of a medicinal product shall be followed by **the standard expression of strength and the standard expression of pharmaceutical form**.[4] The expression of strength shall be stated prior to the expression of pharmaceutical form, as implied by the annexes to the Marketing Authorisation Decree, referred to in the previous sentence. The expression of the strength must always be consistent with the scientific data in the SmPC, PIL, and labelling, and, furthermore, with the expression of strength of other authorised products with the same active substance(s) (the expression of strength shall be governed by more detailed guidance set forth in the EMA QRD Recommendation and the SmPC Guideline). The expression of strength shall always be accompanied by adequate units. In order to maintain uniformity within the EU, strength should be expressed in units of volume or weight, rather than per cent (EMA QRD Recommendation). According to the SmPC Guideline and the Readability Guideline recommendation, for safety reasons micrograms as units in the name of a medicinal product should always be spelled out in full rather than be abbreviated. In case of small immediate packaging, it is permissible to use the abbreviation for micrograms – µg, which is consistent with the EMA stylistic matters. In respect of newly authorised substances in the Czech Republic, the expression of strength must comply with the standards used in the EU. For the products with more than three active substances, or medicinal products where numerical expression would be difficult, the expression of strength is not required to follow the product name.
The pharmaceutical form must be expressed in a significant manner and must comply with the standard terms (see Table X). In compliance with the Annexes to the Marketing Authorisation Decree and the EMA Pre-authorisation Recommendation, SÚKL shall require that the full product name is always shown in the following order: <name><strength><pharmaceutical form> in the product information.
Therefore, the full product name will always be stated in section 1 of the SmPC and labelling and in name section of the PIL (without need for separating the product name from the strength and pharmaceutical form by comma or formatting).
Note: With respect to the previously authorised medicinal products where the strength or the strength and pharmaceutical form are included in the product name, "duplication" of the concerned detail(s) in section 1 of the SmPC and labelling and in the name section of PIL is not required. However, SÚKL recommends MAHs to change/modify such names, i.e. to remove the expression of strength and pharmaceutical form from the product name. Nevertheless, the expression of strength and the pharmaceutical form still follows the product name in the product information (in section 1 of the SmPC and labelling and in name section of the PIL).

Within the scope of individual administrative procedures, SÚKL assesses the proposed name of the medicinal product in the phase of scientific evaluation, not in the validation phase. When SÚKL rejects the name or if the applicant, for marketing reasons, proposes a new name during the procedure, SÚKL shall accept up to 3 new name proposals to be submitted in preferential order as part of the applicant's response. SÚKL shall send its comments, if applicable, within pre-established timetable (in compliance

[4] Cf. Part A item 1 of Annex 3 to the Marketing Authorisation Decree: *"The name of the medicinal product followed by strength and pharmaceutical form shall be provided."* Furthermore, cf. Part A item 2(a) of Annex 4 and Part A item 1(a), Part A item 2 of Annex 5 to the Marketing Authorisation Decree: *"The following details shall be specified in the package leaflet/on the labelling: the name of the medicinal product, followed by its strength and pharmaceutical form and, if applicable, information on whether the product is intended for infants, children or adults."*

with the Act on Pharmaceuticals, Administrative Code, Commission Regulation, and CMDh Best practice guides – see CMDh website).

3) General criteria for the assessment of medicinal product name in relation with its compliance with legal regulations within the scope of marketing authorisation procedure

Each medicinal product name shall meet the criteria stipulated by the provision of Section 4, paragraph 1(a) of the Act on Pharmaceuticals, as referred to above, and, concurrently, shall meet the criteria set forth under the provisions of Section 31, paragraph 5(a), item 4, and Section 37, paragraph 1 of the Act on Pharmaceuticals.

The name of a medicinal product must not be:

- **a)** Misleading with respect to the composition of the concerned medicinal product and its declared therapeutic effects;
- **b)** Liable to confusion with a name of a previously authorised medicinal product or a name submitted in another pending marketing authorisation procedure;
- **c)** Liable to confusion with a name of an active substance;
- **d)** Deceitful or misleading in relation to the target patient group and the Summary of the Product Characteristics;
- **e)** An element of promotional nature.

Ad a) misleading with respect to the composition of the medicinal product and its declared therapeutic effects

The name is is misleading with respect to the composition and therapeutic effects of the medicinal product if it is too similar to or derived from the INN of a substance which is not contained in the product, or if the name contains an INN stem reserved by the WHO for a group of substances into which the active substance contained in the product does not belong.

The name is misleading with respect to the therapeutic effects of the medicinal product if it contains indications which are not described in the Summary of the Product Characteristics, or it highlights only one of many indications or if the name attributes the medicinal product properties which have not been demonstrated.

For examples please refer above – Invented name, b) – i), ii), iv).

Ad b) possible confusion with the name of a previously authorised medicinal product or a name submitted in another pending marketing authorisation procedure

Pursuant to the provision of Section 6, paragraph 2 of the Marketing Authorisation Decree, **the name of a medicinal product must not be liable to confusion with the name of another medicinal product** in print, handwriting or speech. Another medicinal product shall mean a previously authorised product or a product whose marketing authorisation is pending and has not been refused (by final decision) or withdrawn. “Another medicinal product” may also mean a product for which a variation to a marketing authorisation has been accepted and which may be used (in its pre-variation version) until the end of its shelf-life (on the SÚKL's List of authorised medicinal products the marketing authorisation status of such product is indicated as “B”). Also the names of products, whose marketing authorisation has been suspended or has expired, shall be taken into account. In such cases, SÚKL shall consider the possibility of incorrect interpretation of the name with a view to previous use of the medicinal product of a similar name as well as the possibility that a currently suspended marketing authorisation of the medicinal product may be re-established in the future.

Names approved by the EMA Name Review Group (NRG) for medicinal products which will be or have been submitted for marketing authorisation through the EMA centralised procedure, shall be handled equally as the names of products authorised by marketing authorisation procedures carried out by the SÚKL. The aforementioned implies that it is not possible to use the same name for products with different qualitative composition of active substances and that the proposed name of a newly authorised product must not be identical or too similar to the name of a previously authorised product, so as to avoid any confusion (i.e., with a view to possible confusion or misinterpretation, the name must not be misleading and should not contain invented name of a previously authorised medicinal product). When assessing

a potential for confusion, the likelihood of confusion during common handling of the product and the possible consequences of such potential confusion upon patients´ health shall be taken into account.

Additionally, the invented name must not be liable to confusion with the common name of an active substance or excipient or be derived from them, as it would be misleading with respect to the composition and therapeutic effects of the product, or may hinder the creation of new INN (thus it would be inconsistent with the WHO Resolution). When assessing the name of the medicinal product, SÚKL shall also consider the possibility of future authorisation of the product in a new pharmaceutical form. However, even though the name of the medicinal product had been previously assessed as not liable to confusion for a specific pharmaceutical form, it does not mean that it will be automatically acceptable for another pharmaceutical form because such a name – from a practical point of view – may have different parameters when assessing the potential for confusion. A medicinal product containing a prodrug or metabolite of an active substance must bear a different name than a product containing this active substance as it is a product of a different qualitative composition.

The name of the medicinal product should not be identical or liable to confusion with the **names of veterinary medicinal products, medical devices, food supplements, cosmetic products or other products**, including so called umbrella names (see below), as medicinal products, their control, method of manufacture, and documentation are subject to stricter requirements than those governing other kinds of products. SÚKL does not assess possible confusion of the proposed name with the name of another such product within the marketing authorisation procedure. However, if SÚKL finds out that another product exists under a name that may be confused with the name proposed for the medicinal product, with a view to public health protection SÚKL shall notify the applicant proposing the name of such fact and may also state risks that may arise due to potential confusion, if they are known. Such name shall be assessed as unacceptable (with regard to public health protection and patient safety). Nevertheless, it is the obligation of applicants to always carefully consider the possibilities and risks of confusion between the proposed name and the name of another product and, when proposing names, always prefer such option which will safeguard public health protection and patient and consumer safety to the highest possible degree.

If the applicant, despite the warnings of SÚKL, insists upon the proposed name, he has to be aware of his full responsibility for possible breach of the rules of competition (unfair competition)[5] and potential damages that may arise after granting the marketing authorisation of the medicinal product and its placement on the market to those who have already placed other products with a confusingly similar name on the market.

SÚKL shall consider whether it is possible to **use the name of a product whose marketing authorisation has been revoked**, or of a product that may be confused with the name of such product or of a product recalled from the market, when products with a different active substance(s) are concerned. SÚKL shall always consider the time for which the product has been on the market, how well it has been known to the public, what risks might arise from potential confusion of the products, etc. Only having assessed these aspects SÚKL shall approve or refuse such name. SÚKL policy regarding the assessment is similar to that of EMA in the NRG re-use guideline, i.e. it is performed on a “case-by-case” basis.

The use of a product name that may be confused with the name of a product whose marketing authorisation has been revoked or a product that has been recalled from the market, when products with identical active substance, identical or very similar indications, contraindications, interactions, etc. are concerned, is possible. SÚKL shall always consider what risks might arise from possible product confusion. Where a product with an older name has never been placed on the Czech market, its name may be used also for another active substance (and another MAH), if other rules specified in this guideline are met.

The definition of the medicinal product name and other aforementioned rules, according to which the product name must not cause confusion between the product and another one or the possibility of misinterpretation of the name, particularly in relation to the composition, strength and posology of the

[5] Cf. the merits of civil offence of creating a likelihood of confusion and free-riding on the reputation pursuant to Section 2981 and Section 2982 of Act No 89/2012 Coll., the Civil Code, as amended.

product, implies that the product name must not be composed of invented names of two medicinal products, even if these are proprietary names (trade marks). For the aforementioned reasons SÚKL shall not accept the name of another medicinal product (even if it is the trade mark of the concerned MAH) as the identifier of the MAH in a common name of a medicinal product.
The definition of a medicinal product name implies that the name or brand of the MAH is used solely in conjunction with the common name, not with an invented name.

Examples:

Acceptable:	Paracetamol MAH - common name (INN + MAH) Exemplin – invented name
Unacceptable:	Paracetamol Medicin – in case Medicin is the name of another medicinal product, it is not a MAH identifier, but a combination of a common and invented name Exemplin Medicin – the name is a combination of two invented names of authorised medicinal products, Exemplin and Medicin Medicin MAH – a combination of an invented name of a medicinal product and a MAH identifier

Ad c) possible confusion with the name of an active substance

For examples, please refer above – Invented name, b) – ii), iv).

Ad d) + e) deceitful or misleading in relation to the target patient group and the Summary of the Product Characteristics; an element of promotional nature

The aforesaid condition systematically complements the requirement for the medicinal product name being consistent with the composition and therapeutic effects of the product. Therefore, a medicinal product name **must not give a deceitful or misleading impression in relation to the target patient group or the Summary of the Product Characteristics**. This applies e.g. to a situation when the "umbrella name" of the medicinal product contains the qualifier "junior" which gives the impression that the medicinal product is intended solely for a certain group of patients even though the product with respect of its properties (such as the content of the active substance, indications) does not differ from similar products which are not identified in this manner, i.e. in cases when the medicinal product may be used by patients without any age restriction (the qualifier "junior" is hence only of marketing character, but may be misleading for the patient as a consumer; the name with such qualifier would contain elements of promotional nature).

The medicinal product name should also be subject to the requirements stipulated under the provision of Section 37, paragraph 1 of the Act on Pharmaceuticals, i.e. that the data provided on the labelling of a medicinal product must be easily legible, clearly comprehensible, and indelible. Furthermore the labelling of a medicinal product must not bear any elements of promotional nature.

With a view to the aforementioned legal regulations and other documents referred to above, which stipulate requirements for the name of a medicinal product, and also, with a view to the definition of the name and the requirement prohibiting possible confusion and promotional nature of the name of a medicinal product, SÚKL shall consider the use of qualifiers, prefixes and suffixes as well as any other data which are not necessary for the identification of the medicinal product or may be the cause of incorrect interpretation of the name or of the promotional nature of the name (superlatives, multivalent expressions, abbreviations, misleading indications, etc.), unacceptable.

The use of qualifiers may, however, be acceptable for the purposes of distinction among invented names of medicinal products in case of extended marketing authorisation of an existing medicinal product (e.g. with a new pharmaceutical form, flavour, etc.), or in case of so-called umbrella names (for details please refer to section "Umbrella Names" below), where the qualifiers serve for the purposes of distinction among individual products within a particular group. The basic umbrella name should be the name of the product with the simplest composition. The qualifier together with the basic umbrella name must provide information which will facilitate orientation both for the public and for professionals and limit an incorrect use of the medicinal product. Together with the basic umbrella name it shall form the "building blocks", i.e. the first name (used/authorised for the first time) should be without any qualifier. The

qualifiers must absolutely clearly and comprehensibly allow the general public to distinguish the products by their properties.

Examples of some acceptable qualifiers for the purposes of distinction between two invented names (attributes should be in Czech language in order to be comprehensible for the patients, English version is mentioned below in *italics* for explanation of their meaning):

Qualifier:	*Specific property of the medicinal product*
Prolong	A product with extended release compared to the original one (e.g. extended-release tablets)
Rapid	A product with a more rapid onset of effect compared to the original one (e.g. effervescent tablets)
Horký nápoj *(Hot drink)*	A product intended for the preparation of an oral solution which is to be dissolved in hot water before use
Orotab / Distab	A product in the form of orodispersible tablets
Pro děti / Junior *(For children / Junior)*	A product intended solely for paediatric population
Pro dospělé *(For adults)*	A product intended solely for adults
Neo / Novum	A designator of a minor innovation of the medicinal product, such as active substance micronisation
Pomeranč/citron/… *(Orange/ Lemon /…)*	Distinction of flavour (orange, lemon) of an otherwise identical product

Each medicinal product has different properties, and therefore it is not possible to provide a complete list of acceptable qualifiers; it shall always depend on the properties of the particular product whether the particular qualifier is suitable for the product and whether it sufficiently distinguishes the product from the product line (e.g. the qualifier "junior" is acceptable for a medicinal product indicated solely for the paediatric population, but unacceptable in an indication both for the paediatric and adult population, as it would give a misleading impression in terms of the group of patients for which it is intended).

Examples of use of qualifiers for distinguishing of two invented names:

Acceptable:	Exemplin – 500 mg of paracetamol, the first authorised product Exemplin Neo – the product has innovated composition/properties compared to the original one, e.g. it contains granulated paracetamol Exemplin Junior – the product contains paracetamol in a lower strength, indicated solely for the paediatric population Exemplin Rapid – the product contains paracetamol with a more rapid onset of effect, e.g. due to a different pharmaceutical form Exemplin Distab – the product contains paracetamol in the form of orodispersible tablets Exemplin Lemon, Exemplin Orange – the qualifiers distinguish between two flavours of an otherwise identical product
Unacceptable:	Exemplin Junior – for a product containing 500 mg of paracetamol indicated both for adults and for the paediatric population, the name is misleading in relation to the target patient group Exemplin Neo – if the product was identical with the original product Exemplin, the name would be inconsistent with the composition and therapeutic effects and, moreover, it is misleading for the target patient group

With a view to the possibility of incorrect interpretation of the name, particularly in relation to the composition, strength and posology of the product, SÚKL, in compliance with the EMA NRG Guideline, considers inappropriate for names and qualifiers to consist of separate letters and to contain symbols which are not letters, such as +, -, =, *, &, etc. For the same reason SÚKL prefers qualifiers which comprise of at last three letters.

In any of the Czech texts which are submitted for approval the symbol ® or ™ may not accompany the product name. The addition of these symbols behind the trade mark is the full responsibility of the applicant; SÚKL shall not verify their legitimacy and hence they are not to be provided in the approved texts of the SmPC, PIL, labelling or in the SÚKL's decision. In compliance with the provision of Section 31, paragraph 9 of the Act on Pharmaceuticals, industrial property rights are not subject to assessment within the scope of the marketing authorisation procedure. These symbols may be additionally added by the MAH to the approved texts.

Upper case and lower case letters in an invented name are not, with a view to the text formats used in databases of medicinal products (mostly displayed simply in upper case), considered a sufficient distinctive feature. When assessing possible confusion among names, the alternatives of the name EXEMPLIN/Exemplin/exemplin are considered equivalent. The use of upper case in the middle of an invented name could, however, negatively affect the readability and comprehensibility of the name of the medicinal product. The use of upper case inside a name could also intentionally highlight a part of the name. Such name could then be considered an element of promotional nature, and hence would not meet the criteria set forth by law.

4) Special rules for the names of particular types of medicinal products

In compliance with the EMA NRG guideline, SÚKL requires that the names of a fixed combination of substances are sufficiently distinguished from the names of products containing one active substance only, as, in case of confusion, the patient's organism might be exposed to a higher burden, or the treatment efficacy might be reduced. In case of a fixed combination of two active substances SÚKL recommends to separate the names of the active substances in the common name of the medicinal product with a slash (*/*).
Note: If the strength of individual components of the fixed combination product is expressed in units of volume, SÚKL recommends to separate them in the expression of strength (as part of the full product name) with the symbol plus (+).

Examples:

Acceptable:	Losartan/Hydrochlorothiazide MAH *followed by the strength* 100 mg/12.5 mg Lidocaine/Prilocaine MAH *followed by the strength* 150 mg/ml + 50 mg/ml

Nonacceptable:	Losartan + Hydrochlorothiazide MAH 100+12.5 mg Lidocaine-Prilocaine MAH 150/50 mg/ml

In case a new serotype is added to vaccines containing several serotypes, this fact needs to be reflected in the name. The name of the product should be followed by the number of serotypes, the description of which is provided in the product composition (e.g. “Invented name” X serotypes …). The same procedure shall be employed in the naming of vaccines containing various types of antigens when a new type of antigen is added. New vaccines are authorised primarily through the procedure laid down by Regulation No 726/2004. This requirement complies with the EMA NRG Guideline.

Radiopharmaceuticals are considered to be a special group of products in terms of names, particularly due to the different method of handling those products. The name of a radiopharmaceutical must not contain the name or symbol of an isotope which is not contained in the product. With a view to the specifics of this indication group SÚKL policy regarding the assessment of their names is in compliance with the EMA NRG Guideline.

Example:

Acceptable:	Sodium fluoride (18F) MAH – an INN does not exist, this is a pharmacopoeial name with the specification of the isotope number and element symbol in the format: *<Radionuclide> < (isotope number and element symbol)> <ligand or carrier> <MAH>*

Common names of homeopathic products and herbal medicinal products may be formed by the Czech or Latin pharmacopoeial name or commonly used name if no pharmacopoeial name exists, accompanied by the name or a trademark of the marketing authorisation holder. The aforesaid rules

shall reasonably apply to homeopathic products. A name which has been well established in homeopathic practice may be used instead of a Latin name (preferred pharmacopoeial names in the German Pharmacopoeia, or, if applicable, in the French Pharmacopoeia), if followed by the common name of the substance of which the product is made in the PIL and on labelling.
The expression of strength for herbal medicinal products shall be assessed in compliance with the Guideline on herbal products.

Examples:

Acceptable:	Kalium muriaticum MAH – homeopathic name accompanied by the MAH's identifier Acidum phosphoricum MAH – Latin name of the active substance followed by the MAH's identifier

Pursuant to the Guideline on medicinal gases, the names of medicinal gases must contain the word "medicinální" (*medicinal*). For invented names of such products it shall be sufficient if such name is in the SmPC, PIL and on the labelling followed by the standard expression of the pharmaceutical form: "medicinální plyn, stlačený" (*medicinal gas, compressed*); "medicinální plyn, kryogenní" (m*edicinal gas, cryogenic*); "medicinální plyn, zkapalněný" (*medicinal gas, liquefied*).

Example:

Acceptable:	Oxid dusný medicinální MAH (*Nitrous oxide medicinal MAH*) – common name of the gas followed by the word "medicinal" and the MAH's identifier

In case the active substance is present in authorised products in more than one form (base, salt, ester), SÚKL in line with other EU regulatory authorities recommends that common names of medicinal products containing various forms of the active substance are distinguished by specifying the particular salt/form of the active substance in the name of the medicinal product.
In case the active substance is present in authorised products in one form only, it is not necessary to distinguish the names by specifying the particular salt in the name of the medicinal product.
However, if a product using the common name of a particular salt has already been authorised in the Czech Republic, or such name has been approved by the EMA NRG group, then with a view to the safety in prescribing and using the medicinal product, SÚKL requires that uniformity for the market is maintained, i.e. that the common name of a product containing the same active substance is acceptable only if it contains the name of the particular salt.

Examples:

Acceptable:	Levocetirizine MAH – the product contains levocetirizine dihydrochloride, levocetirizine is not contained in authorised products in another form, it is not necessary to specify the particular salt in the common name Mycophenolate mofetil MAH – the product contains mycophenolate mofetil and products containing mycophenolic acid sodium salt with different indications have also been authorised
	Perindopril MAH – the first product presentation on the market, contains perindopril-erbumine Perindopril arginine MAH – the product contains perindopril arginine, a distinction from previously authorised products containing perindopril erbumine on the market is needed
Unacceptable:	Mycophenolate MAH – the product contains mycophenolate mofetil, the name is not consistent with the names of authorised products containing mycophenolate mofetil, and therefore is misleading in relation to the composition of the medicinal product Perindopril MAH – the name is misleading for a product containing perindopril-arginine in relation to medicinal product composition, as authorised products called Perindopril MAH contain perindopril erbumine

The assessment of names authorised through the centralised procedure is not within the exclusive competence of SÚKL; these names are assessed in cooperation with the EMA NRG group in compliance with the rules stipulated by the EMA NRG Guideline. In view of the fact that the decisions

regarding the marketing authorisation of products authorised by centralised procedure are granted by the European Commission and not by SÚKL, the same name cannot be used for products authorised by other than the centralised procedure (national, mutual recognition and decentralised procedures), not even in case of so called umbrella names.

Umbrella Names

Generally, umbrella names are names of products from the same therapeutic group, of the same marketing authorisation holder, whose basic invented name is the same and complemented with another part (qualifier), which provides the patient or healthcare professional the information which will facilitate orientation and will prevent incorrect interpretation of the name or incorrect use of the product. The basic prerequisite for using an umbrella name is that all products within the particular group contain at least one identical active substance.

The basic umbrella name must be complemented with another part of the name – a "qualifier" (see above) which will provide adequate distinction among individual products. This qualifier should describe a typical property in which the product of the given group differs from all other medicinal products within this group (it is recommended e.g. to specify the name of an added active substance in a manner which will not violate the aforementioned rules, e.g. Medicin s vitaminem C (*Medicin with ascorbic acid*), if the indication of the product does not change and the substance is well known to the general public). In case more substances are added to the basic product, such fact should be reflected in the name (Medicin s vitaminem C a kofeinem) (*Medicin with ascorbic acid and caffeine*).

The complementing parts of product names must be clear and comprehensible to the general public.

It is recommended that the specification is provided in the Czech language (another language can be used only if the expression has been domesticized on the Czech market).

Examples:

Acceptable:	Exemplin – contains 500 mg of paracetamol Exemplin Plus – the product contains a combination of paracetamol and caffeine, similar indications as the original product Exemplin Exemplin Grip – the product contains a combination of paracetamol and phenylephrine hydrochloride and is indicated for the treatment of flu and cold symptoms Exemplin pro děti (*for children*) – a syrup, contains a lower dose of paracetamol and is indicated only for the paediatric population
Unacceptable:	Exemplin proti bolesti v krku (*for sore throat*) – in case a product with the basic name "Exemplin" has not been authorised, it is not an umbrella name, the qualifier "na bolest v krku" only prolongs the invented name (the invented name Exemplin without qualifier would be acceptable) Exemplin proti bolesti v krku (*for sore throat*) – if the product with the basic umbrella name "Exemplin" contains active substance *paracetamol*, the umbrella name "Exemplin" will not be acceptable for a product containing different active substance, e.g. *flurbiprofen* Exemplin Neo – for a product containing ibuprofen, if the original product Exemplin contains paracetamol, then the proposed name is inconsistent with the composition and therapeutic effects of the product and is misleading for the target patient group Exemplin Neo – for a product containing an active substance added to the original product Exemplin, the product is not a minor innovation of the original product, but has e.g. different indications or adverse reactions, the qualifier Neo is not appropriate and could be misleading for the target patient group in relation to the composition and therapeutic effects of the product

With a view to the risks associated with umbrella names, SÚKL prefers new invented names for new products.

Each name of a medicinal product is assessed individually, considering the potential risks.

5) Preliminary assessment of medicinal product name

In case that an application for preliminary assessment of a medicinal product name is submitted, SÚKL shall issue a written expert opinion for which the applicant is obliged to cover the costs of expert activities as referred to by Decree No 472/2008 Coll., as amended (for details, please refer to UST-29, as amended, available on the SÚKL's website, code of payment O-002). This opinion is valid only at the time of its issue, as the proposed name is, *inter alia*, compared to existing names or names of medicinal products whose application for marketing authorisation is pending.
In order that the name could be assessed, the applicant submits full product name, i.e. the proposed product name followed by the expression of strength and pharmaceutical form in the application for preliminary name assessment together with the detailed information on the properties of the product, for which the name is being proposed (anticipated indication, target patient group, composition of the medicinal product; ideally draft SmPC, if available to the applicant, should be provided) and a proof of reimbursement of costs. Applications which do not contain the specification described above shall be considered invalid and SÚKL shall request amendment within the aforementioned scope. A single application may contain up to three proposed names for a single medicinal product.

It is recommended to send the applications for preliminary name assessment electronically to email address: posta@sukl.cz. Afterwards, SÚKL shall electronically send its expert opinion to the applicant, stating whether the proposed names are acceptable or not. Such opinion is valid only as of the date of its issue and no appeal can be filed against it.

6) Reporting of medication errors related to similarity of product names

SÚKL calls upon all stakeholders and public to report any medication errors related to similarity of the names of medicinal products, especially mix-up of medicinal products, whether the error occurs at the level of prescription, dispensing or use of the medicinal product, with special emphasis on medication errors which result or could result in adverse drug reaction or harm for patients. Reports can be sent by e-mail to addresses nazvy@sukl.cz and farmakovigilance@sukl.cz, preferably both.

7) Medicinal product name in Braille

Pursuant to Section 37 of the Act on Pharmaceuticals, the name of a human medicinal product must be stated on the outer packaging also in Braille, unless stipulated otherwise in the marketing authorisation. The technical parameters for Braille shall be governed by the EN ISO 17351 Packaging – Braille on Packaging for Medicinal Products (ISO 17351:2013) standard.
The outer packaging of a medicinal product must include the name of the product in Braille as it was approved by SÚKL in section 16 of the labelling. The name in Braille must be expressed in a manner allowing clear identification of the concerned medicinal product.

- For medicinal products which have been authorised in a single strength only it is acceptable for the name of the product in Braille to contain only the invented or common name without the expression of strength and pharmaceutical form.
- In case the product has been authorised with several strengths in a single pharmaceutical form, it is necessary for the name in Braille to contain the invented or common name followed by the expression of strength. The expression of pharmaceutical form is not necessary in this case.
- If the product has been authorised in several strengths and/or several pharmaceutical forms, it is necessary for the invented or common name to be followed by the expression of strength and pharmaceutical form.

Upper and lower case letters shall not be distinguished within the scope of the assessment of the name in Braille.
SÚKL accepts inclusion of other information in Braille on the outer packaging of the medicinal product (expiry, whether the product is intended for children or adults, etc.).

Note: If the expression of strength containing the units "micrograms" follows the product name in Braille, SÚKL in justified cases (such as lack of space on the packaging) will not insist on the provision of the full word "micrograms", but will accept their expression in Braille abbreviated as "mcg". Furthermore, SÚKL shall accept that simplified names of pharmaceutical forms as per Table X are used in the name in Braille.