REG-29 version 5 Methodology of Medicinal Product Name Acceptability Assessment for the Purposes of Marketing Authorisation Procedure

This Guideline supersedes Guideline REG-29 version 4 as of 1 July 2025.

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This Guideline has been issued in order to facilitate navigation in the area of medicinal product names (hereinafter referred to as "names") and rules governing name creation and assessment with regard to public health protection, patient safety, and legislative requirements.

The Guideline is issued by the State Institute for Drug Control (hereinafter referred to as the "Institute" or "SÚKL") in compliance with the below-listed legal regulations.

The Guideline is of recommendatory in nature.

Nevertheless, its content is based, *inter alia,* upon the requirements stipulated by legislation and EMA guidance, which are legally binding.

The Institute reserves the right to adjust the assessment practice based on experience or newly established safety concerns.

The guideline on medicinal product name acceptability assessment shall apply to all medicinal products authorised via the national and MR/DC procedures, regardless of their classification for supply.

This Guideline is not applicable to the names of medicinal products authorised via the centralised procedure (the names of these products are governed by the EMA/CHMP/287710/2014 guideline).

1. Legal Regulations and Associated Sources

- 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")
- Decree No 228/2008 Coll., on Marketing Authorisation of Medicinal Products, as amended (hereinafter referred to as the "Marketing Authorisation Decree")

- Directive 2001/83/EC, on the Community code relating to medicinal products for human use (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 500/2004 Coll., the Code of Administrative Procedure, as amended (hereinafter referred to as the “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 “NRG EMA Guideline”)
- Resolution of the World Health Organisation (WHA 46.19) (hereinafter referred to as the “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 “QRD EMA Recommendations”)
- Guideline on summary of product characteristics (SmPC) Notice to Applicants (hereinafter referred to as the “SmPC Guideline”)
- 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 the “Guideline on Readability”)
- European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure (hereinafter referred to as the “EMA Pre-authorisation Advice”)
- Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products EMA/287539/2005 (hereinafter referred to as the “Guideline on herbal products”)
- Guideline on medicinal gases: pharmaceutical documentation CPMP/QWP/1719/00 (hereinafter referred to as the “Guideline on medicinal gases”)
- Table X: Standard names of dosage forms, routes of administration and packaging, as amended – SÚKL guideline based on the "Standard Terms for dosage forms, routes of administration and containers" (ISBN 92-871-5734-0). Coordination is safeguarded by the working group of the European Directorate for the Quality of Medicines and HealthCare (EDQM) (SÚKL website: – Pharmaceutical industry/Medicines/Marketing authorisation of medicines/Details of marketing authorisation/Table X – Standard names of dosage forms, routes of administration and packaging) (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”)
- Q&A – Generic Applications (CMDh/272/2009)
- 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”)

General Legislative Requirements:

- Section 4(1) of the Act on Pharmaceuticals: The name of a medicinal product shall mean 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**. A common name shall mean the international non-proprietary name recommended by the World Health Organisation or, if one does not exist, the commonly used name;

- Section 31(5)(a)(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(1) or whose application for marketing authorisation is pending with the Institute or the Veterinary 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 an EU 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 product characteristics;
- Section 37(1) of the Act on Pharmaceuticals: Data shown on the outer and immediate packaging of a medicinal product for human use, with the exception of homeopathic products authorised pursuant to Section 28, must be consistent with the approved summary of product characteristics. The implementing legal regulation stipulates the scope of data to be shown on the outer and immediate packaging of a medicinal product for human use, data to be shown on small and special types of packaging, including packaging of medicinal products containing radionuclides, as well as the conditions governing the provision of data for identification of the medicinal product for human use by an internationally recognised identification standard which serves for the purposes of electronic processing and is consistent with the requirements of the standard coding system, unless a unique identifier is concerned, and, where appropriate, the statement of the established classification of the medicinal product for human use for the purposes of supply. **Data shown on the packaging of the medicinal product for human use must be** easily legible, **comprehensible**, and indelible. The packaging of medicinal products for human use must show the code allocated as per Section 32(5). **No elements of promotional nature shall be permissible on the packaging of a medicinal product for human use**. The name of the medicinal product for human use must be provided on the outer packaging also in Braille, unless stipulated otherwise in the Marketing Authorisation;
- Section 6(2) of the Marketing Authorisation Decree: The assessment of potential name confusion as referred to under Section 31(5)(a)(4) of the Act on Pharmaceuticals shall consider, in particular, whether the **name in its printed or spoken form may be confused with the name of another medicinal product for human use**. The assessment shall take into account the likelihood of confusion in normal handling of the medicinal product for human use and the consequences of the potential confusion for the health of patients;
- Art. 6(1) of Regulation No 726/2004 of the European Parliament and of the Council: **Each application for the authorisation of a medicinal product for human use shall specifically and completely include** the particulars and documents as referred to in Articles 8(3), 10, 10a, 10b or 11 of, and Annex I to, Directive 2001/83/EC. The documents must include a statement to the effect that clinical trials carried out outside the European Union meet the ethical requirements of Directive 2001/20/EC. These particulars and documents shall take account of the unique, Community nature of the authorisation requested and, **otherwise than in exceptional cases relating to the application of the law on trade marks, shall include the use of a single name for the medicinal product**;
- Art. 1(20) of Directive 2001/83/EC of the European Parliament and of the Council: Name of the medicinal product shall mean: The name, which may be either an invented name not liable to confusion with the common name or a common or scientific name, together with a trade mark or the name of the marketing authorisation holder;
- Art. 1(21) of Directive 2001/83/EC of the European Parliament and of the Council: Common name shall mean: The international non-proprietary name recommended by the World Health Organization, or, if one does not exist, the usual common name;
- Art. 3(3)(c) of Regulation No 726/2004 of the European Parliament and of the Council: The generic medicinal product (note: to a centrally authorised original product) is authorised under the same name in all the Member States where the application has been made. For the

purposes of this provision, all the linguistic versions of the INN (international non-proprietary name) shall be considered to be the same name.

2. Medicinal Product Names – Definitions and General Principles

The medicinal product name forms an integral part of the marketing authorisation (hereinafter referred to as "MA") and its proper establishment is an important means of individualisation of the medicinal product. The name of the medicinal product is defined 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 provision of the Act on Pharmaceuticals contains not only the definition of the name, but also basic criteria governing its content. The name of a medicinal product may hence be only:

- 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 (hereinafter referred to as "MAH").

The name may hence assume the form of an **invented name** or **common** or scientific name accompanied by the MAH´s name or trade mark. In product information, the name of the medicinal product is followed by the standard expression of strength with units and the standard expression of the pharmaceutical form (as per Table X). The name together with the strength and pharmaceutical form is the **full product name**.

Fig. 1: Full product name

When assessing whether the medicinal product name (both common and invented) is liable to confusion, the Institute shall always assess the **full product name**, i.e., the name followed by the expression of strength (together with units) and pharmaceutical form specified by the applicant in section 1 of the SmPC. Nevertheless, for the purposes of the marketing authorisation procedure, in the application for marketing authorisation (and Annex 5.19, if applicable), the applicant shall specify only the product name (without strength and pharmaceutical form).

Expression of Strength

The information about strength shall precede the expression of the pharmaceutical form, as implied by the texts of Annexes to the Marketing Authorisation Decree referred to on page 2. The expression of strength must always be consistent with the scientific data provided in the SmPC, PL and on the labelling, as well as with the expression of strength of other authorised products containing the same active substance(s) in the same or similar pharmaceutical form (the expression of strength shall be governed by detailed guidance provided in the QRD EMA Recommendations and the SmPC Guideline). The expression of strength must be always accompanied by the relevant units. In order to maintain uniformity within the EU, the strength should be expressed in units of volume or weight rather than as percentage (QRD EMA Recommendations). In compliance with the SmPC Guideline and with the Guideline on Readability, for safety reasons micrograms as units in the expression of strength should be always spelt out in full. In case of small immediate packaging, it is permissible to use the abbreviation for micrograms – µg, which complies with the EMA stylistic matters. For substances newly authorised in the Czech Republic, the expression of strength must be consistent with the standards used in the EU. For products containing more than three active substances or products where numeric

expression would be difficult, the name of the medicinal product does not have to be followed by the expression of strength.

Expression of Pharmaceutical Form

The expression of the pharmaceutical form must comply with the Standard Terms (Table X refers). In compliance with the Annexes to the Marketing Authorisation Decree and the EMA Pre-authorisation guidance, the Institute shall require that the full product name be specified in the product information always in the following order: <name> <strength> <pharmaceutical form>.

In section 1 of the SmPC, on the labelling, and in the PL introduction, it is hence always necessary to provide the full product name (without any punctuation marks or formatting separating the name, strength, and pharmaceutical form).

3. When to Submit the Name Proposal of a Medicinal Product

3.1. New Marketing Authorisation

Within the scope of individual administrative procedures, the Institute assesses the submitted proposal of the medicinal product name in the assessment phase not in the validation phase. If the Institute declines the name or if the applicant, for marketing reasons, proposes a new name during the procedure, the Institute shall accept up to 3 name proposals in preferential order for each response/submission. The Institute shall send objections, if applicable, within predefined timelines (in compliance with the Act on Pharmaceuticals, Administrative Code, Commission Regulation and the CMDh Best practice guides – see CMDh website).

National Procedure:

In respect of applications for new marketing authorisation, the name of the medicinal product forms part of the submitted documentation (module 1.2) and it shall be specified in the Application Form (eAF) under section 2.1.

MR/DC Procedure:

In respect of applications for new marketing authorisation, the name of the medicinal product forms part of the submitted documentation (module 1.2) and it shall be specified in the eAF under section 2.1 (if the proposed name is identical for all Member States), or in Annex 5.19 (if the proposed name differs in individual Member States).

The name of the medicinal product should be approved prior to the completion of the European phase of the procedure (i.e., prior to the issuance of the End of Procedure). The assessment of name acceptability in the national phase of the procedure is permitted by the Institute only in exceptional cases, where no acceptable name has been proposed in the course of the European phase of the procedure. Where the name is accepted in the European phase of the procedure, it is no longer possible to change the name in the national phase, and hence assessment of another name cannot be applied for, either.

3.2. Variations to Marketing Authorisations

Following product authorisation, the name of the medicinal product may be changed via application for type IB variation to marketing authorisation of the relevant classification. For medicinal products authorised via the MR/DC procedures, a MRP variation shall be submitted, and for nationally authorised medicinal products, a national variation with the relevant payment of the cost reimbursement and administrative fee shall be submitted.

Once the medicinal product obtains marketing authorisation, its name may be changed only via the relevant variation to marketing authorisation, as mentioned above. The name cannot be changed in any other administrative procedures (e.g., at the time of MA transfer or renewal).

4. Assessment Criteria Governing Medicinal Product Name Assessment

The following criteria should be considered generally applicable rules, whereas each name is assessed individually. The conclusions of name assessment for a particular medicinal product are not automatically applicable to the assessment of a name of another medicinal product.

In the assessment of acceptability of proposed names, emphasis is placed upon public health protection and patient safety, taking into account development in the pharmaceutical industry.

4.1. General Principles Governing the Assessment of Medicinal Product Name Acceptability

The name of the medicinal product must not be:

a) inconsistent with the composition of the concerned medicinal product and its declared therapeutic effects;
b) liable to confusion with the name of a previously authorised medicinal product or a product whose marketing authorisation is pending;
c) liable to confusion with the name of the active substance;
d) deceitful or misleading with regard to the target patient group and the summary of product characteristics;
e) an element of promotional nature;
f) a combination of an invented and common or scientific name accompanied by the MAH´s name or trade mark.

Examples	
Acceptable:	
	Paracetamol MAH – common name
	Exemplin – invented name
Unacceptable:	
	Paracetamol Medicin – in case "Medicin" is the name of another medicinal product, it is not a MAH´s 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 the medicinal product and a MAH´s identifier

Liability to Confusion with the Name of Another Product

The name in its printed, written or spoken form must not be liable to confusion with the name of another medicinal product. Another medicinal product shall mean a previously authorised product (that obtained national or centralised MA) or a product whose marketing authorisation is pending and the application has not been refused by final decision. "Another medicinal product" shall, also, refer to an authorised product for which a variation to MA has been approved and which may be used in its pre-variation version until the end of its shelf-life (i.e., a medicinal product with MA status "B" in the Institute´s Drug database). Furthermore, names of products whose MA has been suspended or expired shall be also taken into consideration. In those cases, the Institute shall consider the possibility of incorrect interpretation of the name with regard to the previous use and characteristics of the

medicinal product bearing a similar name as well as the possibility of future resumption of a suspended authorisation of a medicinal product.

The Institute approaches the assessment of the **use of a 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 a product recalled from the market, where products with a different active substance are concerned, analogously to EMA in the NRG re-use guideline, i.e., on a "case-by-case" basis. The Institute always assesses the period for which the product was on the market, how well it was known to the public, what risks could be implied by potential product confusion, etc., and only having addressed these circumstances, it approves or refuses the name in question.

The use of the product name that may be confused with the name of a product whose MA has been revoked or of a product recalled from the market, where products with the same active substance, same or very similar indications, contraindications, interactions, etc. are concerned, is possible. Nevertheless, the Institute always assesses the risks that could be implied by potential confusion of the concerned products. If the product with the older name has never been placed on the Czech market, its name may be used also for another active substance (and for another MAH), if other rules contained in this guideline are observed.

The approach to names approved by the Name Review Group (NRG) EMA working group for medicinal products in respect of which application for MA via the EMA centralised procedure will be or has been submitted, is the same as that to names of products in MA procedures processed by the Institute. To avoid doubt, the aforementioned implies that the same name cannot be used for products of different qualitative composition of active substances (except for umbrella names – see chapter 8) and that the proposed name of a newly authorised product must not be identical with or exhibit such similarity to the name of a previously authorised product that could cause any confusion (i.e., due to liability to confusion or incorrect interpretation; the name must not be misleading; and should not contain an invented name of a previously authorised medicinal product). In the assessment of potential confusion, the likelihood of confusion during regular handling of the product and the consequences of potential confusion for the health of patients is taken into account.

In the assessment of potential medicinal product confusion, the Institute takes into account, *inter alia,* the following characteristics of the medicinal products:

- indications,
- target patient population,
- intended healthcare professional (such as identical specialty of the prescribing physician, administration at a specialised medicinal facility, etc.),
- pharmaceutical form,
- route of administration,
- strength,
- the degree of complexity in handling the medicinal product, which may affect its correct use, e.g., instructions for use, storage conditions, used technologies, previously identified medication errors, standard instructions for healthcare professionals,
- set up dispensing, posology, and preparation and use/administration of the product, where applicable,
- the existence of control mechanisms, i.e., procedures associated with the prescribing, dispensing, preparation or administration that can reduce the risks of medication errors, such as procedures to be followed during reconstitution of powder preparations, patient education in case of chronic disease therapy, highly specialised manufacturing and/or personalised processes for handling of advanced therapy medicinal products or radiopharmaceuticals,
- classification for supply (e.g., medicinal product subject to medical prescription, OTC products),
- the degree of similarity of the name versus potential risks for the patient in case of product confusion.

The name of the medicinal product should not be the same as or liable to confusion with the **names of veterinary medicinal products, medical devices, food supplements, cosmetic products or other types of products**, which applies also to so called umbrella names (see below), as medicinal products, their control, method of manufacture, and documentation are subject to completely different requirements than other types of products. Although, in the course of the administrative procedure, the Institute does not assess the potential for confusion of the proposed name with the name of another product, with regard to public health protection, if the Institute in the course of the procedure learns of the existence of another product bearing a name that could be confused with the name proposed for the medicinal product, it alerts the person submitting the proposal of this fact and, if applicable, specifies the risks that could arise from the potential product confusion, if known thereto, assess the name as unacceptable (in order to safeguard public health protection and patient safety). It is, however, the obligation of the applicant, to always assess the possibilities and risks of potential confusion of the proposed name with the name of another product and, when submitting proposed names, to always prefer such alternative that will safeguard public health protection and patient and consumer safety to the highest degree practicable.

Should the applicant insist on the proposed name despite the alert from the Institute, they must be aware of their full responsibility for potential breach of the rules of competition (unfair competition) and potential damage that may arise after the authorisation and placement of the medicinal product on the market to those who have already been placing other products with names liable to confusion on the market.

In any of the Czech texts submitted for approval, the name of the medicinal product cannot be accompanied by the symbol ® or ™. Showing these symbols behind the trade mark is the full responsibility of the applicant; the Institute does not verify their legitimacy, and hence these are not to be provided in the approved texts of the SmPC, PIL, on the labelling or in the Institute´s decisions. In compliance with the provision of Section 31(9) of the Act on Pharmaceuticals, industrial property rights are not subject to assessment within the scope of the MA procedure. The MAH may add these symbols to the approved texts later on. It is possible to show the trade mark symbols ® and ™ on mock-ups (and hence also on the packaging of the product placed on the market), nevertheless, this is fully the competence and responsibility of the applicant/MAH.

4.2. Common Name – Assessment Criteria

Generally, a common name is defined as the international non-proprietary name (hereinafter referred to as the "INN") recommended by the WHO or, where no such international non-proprietary name exists, the commonly used name together with the name or trade mark of the marketing authorisation holder (hereinafter referred to as the "MAH identifier").

With a view to the aforementioned, where a common name is used, the following rules should be observed:

- If there is an INN recommended by the WHO, it is required by the WHO Resolution to be stated in the common name of the product in the form published on the WHO INN list (e.g., not using abbreviations), in order to avoid the risk of incorrect interpretation of the name or confusion of medicinal products.
- If there is a modified INN (INNM) recommended by the WHO, it is required to be stated in the common name of the medicinal product in the form published by the WHO (e.g., not using abbreviations).
- If there is no INN, according to the Institute, it is possible to use the preferred common name in the following order of preference:
  - pharmacopoeial name (as per the Czech Pharmacopoeia, European Pharmacopoeia),
  - the name used by professionals, listed as preferred scientific name in the database of the Institute,

- in exceptional cases, it is possible to use also a name used by professionals which does not correspond to the preferred scientific name listed in the database of the Institute, but which has been established in the Czech milieu and/or is more comprehensible for the patient – such names are assessed on a case by-case basis).

- In the Czech Republic, linguistic versions comprehensible for the Czech consumer (common Czech and English names) are acceptable; for homeopathic products and some herbal medicinal products also Latin versions may be used.
- The MAH identifier should correspond to the full or part of the official name of the MAH.
- The MAH identifier cannot be an acronym (abbreviation), unless it is the MAH´s registered trademark which clearly refers to the MAH and helps its identification. Nevertheless, in such a case, the MAH has to submit a certificate of ownership of such trademark. The use of such an acronym, however, must not be of promotional nature and must not be inconsistent with use of the active substance in association with the proposed therapeutic indication.
- With a view to safeguarding easier identification of medicinal products, and hence also with a view to safe use and prescription, the Institute recommends that each MAH uses only one identifier in common names of medicinal products. Nevertheless, in justified cases, the Institute may permit more than one identifier for a single MAH (for instance: if the MAH already has an authorised product with a common name and applies for new MA of a product with the same active substance in the same strength and pharmaceutical form).
- The aforementioned implies that with a transfer of the marketing authorisation to a new MAH, the Institute requires submission of an application for change to the common name of the medicinal product (MAH identifier), because, as required by law, the identifier has to identify the MAH (i.e., the current marketing authorisation holder).
- Pursuant to the NRG EMA Guideline, punctuation marks in between the INN and the MAH identifier are not acceptable, except for fixed combinations of two or more active substances, for which the Institute recommends that the active substance names be divided by slash ("/").

  Note: If the strength of individual product components is expressed in units of volume, the Institute recommends to use the plus symbol ("+") to separate them in the expression of strength in product information (as part of the full product name).

Common name examples	
Acceptable – INN exists:	
	Paracetamol MAH
	Paracetamol/ibuprofen MAH
Acceptable – INN does not exist, but pharmacopoeial name does exist:	
	Glucose MAH
Acceptable – INN or pharmacopoeial name does not exist, and hence it is necessary to use preferred scientific name:	
	Selene MAH
Unacceptable common name examples:	
	Paracetamol – INN without MAH identifier
	Paracet MAH – abbreviated INN, not a common name

	Paracetamolum MAH – name of the active substance in Latin

4.3. Invented Name – Assessment Criteria

Content Words

An invented name is only a truly invented (fictitious) one-word name, rather than a content word or commonly used name (as such name would be contrary not only to the legal definition of a medicinal product name, but also to the requirements governing the data to be shown on medicinal product packaging). An invented name derived from a content word in the Czech or English (or another) language may, however, be considered acceptable by the Institute, providing such name is not promotional and is not misleading in terms of the product composition and therapeutic effect and in relation to the target patient group and the summary of product characteristics.

The invented name must not be offensive or carry negative or vulgar connotations, particularly in cases where the invented name has been created in a manner giving it meaning in the Czech language.

Reflecting the Pharmaceutical Form

In the assessment of the name of a medicinal product, the Institute considers also the possibility of a future authorisation of the product in a new pharmaceutical form. Despite the aforementioned, if the name of the medicinal product was previously assessed as not liable to confusion for a particular pharmaceutical form, it does not mean that it will be automatically acceptable for another pharmaceutical form, because the name in another pharmaceutical form may bear other parameters of potential confusion in terms of practical use. A medicinal product containing a prodrug or a metabolite of a particular active substance must bear a different name than a product containing this active substance, because the qualitative composition of both products differs.

Derivatives from Other Names

An invented name of a medicinal product must not contain the full name of another medicinal product. Potential exceptions are considered individually, with regard to the degree to which they are liable to confusion and similar. In case where invented names do not share the same letters in the same sequence, however, confusion may be assessed as likely to happen, as the way the human brain perceives the name (so called cognitive error associated with at least moderate degree of similarity in printed, written or spoken form) is also taken into consideration.

Derivatives from MAH Name

Invented names significantly similar to the name of a pharmaceutical company or in which a MAH´s name is contained and dominant or noticeably referred to are not acceptable. Such name could be considered promotional, or possibly even misleading if it reminded of the name of another medicinal product marketing authorisation holder.

Derivatives from Indication

Generally, the invented name of a medicinal product may be partially derived from the indication. Nevertheless, in case of a medicinal product with multiple indications, the name of which would be derived only from some of the indications, such name could be considered misleading, and therefore unacceptable.

Comprehensibility of Names and Special Characters

Very short invented names composed of e.g., a chain of vowels or consonants, may be considered unacceptable by the Institute, as they may not be sufficient for proper identification of medicinal

products. For this reason, the Institute recommends that invented names be composed of at least four letters.

Furthermore, the proposed invented name should not use symbols, dose designations and medical abbreviations commonly used for prescription communication, as their presence in the name could cause, for instance, medication errors.

The invented name of a medicinal product must not be composed solely of acronyms (i.e., abbreviations formed from the initial letters of words) and must not contain numerals or non-letter characters such as +, -, =, *, &, etc. It may not contain diacritic marks (except for umbrella name qualifiers – see below).

Furthermore, the Institute discourages the use of invented names that are difficult to pronounce, as such names could lead to incorrect identification of the medicinal product.

Upper and Lower Case in the Name

Upper and lower case inside an invented name is not considered a sufficiently distinctive feature with a view to medicinal product database formats (usually displayed only in upper-case). When assessing potential name confusion, the name presentations EXEMPLIN/Exemplin/exemplin are considered equivalent. The use of upper case inside an invented name is hence irrelevant and such name will be assessed as if all characters were of the same size (e.g., ExemPlin will be considered as EXEMPLIN). The use of upper case inside the name in product information is governed by the EMA stylistic matters guidance.

Medical Device Identification as Part of the Name

If the invented name of a medicinal product is accompanied by the name of a medical device (e.g., the identification of an inhaler type or pre-filled pen type), it must not be, in its printed, wiritten or spoken form, liable to confusion with the name of another medicinal product. The name of the medical device is not considered an element of sufficient distinction from other medicinal products.

In case a one-word name is accompanied by the name of a medical device, the one-word name requirement shall not apply.

Graphic Presentation of the Name

The assessment of an invented name acceptability also takes into consideration the design of the packaging, particularly where the invented name is considered similar to another invented name belonging to the same MAH. The requirements governing the graphic presentation of the name on the packaging are defined in SÚKL guideline REG-96.

Similarity with International Non-proprietary Names (INNs)

An invented name must not contain an international non-proprietary name (INN) recommended by the World Health Organisation (hereinafter referred to as “WHO”) or its stems (hereinafter referred to as “INN stems”, which are reserved by WHO for a particular group of substances – see WHO document “Use of stems in the selection of International Nonproprietary Names (INN) for pharmaceutical substances”). An invented name should not be significantly derived from an INN, either. This is because it could cause misinterpretation and the name could be considered the name of a new active substance or imply that the product is of different composition and exhibits different therapeutic effects. Failure to observe this rule stipulated by the WHO Resolution could corrupt the long-established WHO INN structuring system.

In case of fixed combinations of active substances, the invented name must not be significantly derived from the INN of one of the active substances only, as it would be misleading in terms of composition and therapeutic effects.

The assessment of similarity with INNs is driven by two criteria – similarity with own or different INN (i.e., whether the name is similar to the INN of the substance contained in the product, or not) and the presence of an INN stem.

In the assessment of invented name similarity with INNs, the Institute generally employs the "50% similarity rule" in its decision-making, in order to identify cases where 50 % or more of the invented name consists of parts of an INN and/or 50 % or more of an INN is included in the proposed invented name. Other elements subjected to assessment are: shared letter sequence, letter order and position in the name, and whether the proposed invented name contains the INN stem for the same or different pharmacological/chemical property.

In the assessment of similarity with INNs, phonetic similarity may also come into question, such as that between: "i" and "y", "d" and "t", "s" and "z", etc. For this reason, the Institute encourages MAHs to consider potential similarity with (proposed, recommended or revised) INNs and/or the presence of an INN stem prior to submitting the proposed name.

With a view to the aforementioned, the Institute assesses each proposal on a case-by-case basis, and therefore, it is not possible to state that a similarity of less than 50 % is automatically acceptable and, likewise, similarity greater than 50 % is automatically unacceptable.

Invented name examples	
Acceptable – invented name of a medicinal product containing paracetamol:	
	Parhau – the name is invented, it is not liable to confusion with the name of another medicinal product or INN, it does not contain INN stems, it is inconsistent with the product composition or therapeutic effects, it is not misleading in terms of the target patient group or the SmPC, it is not of promotional nature
	Levpar – the name contains content word "lev" (which means "lion" in Czech), which, however, does not create the impression of being promotional, and it is not misleading in terms of the product composition and therapeutic effects
Acceptable – invented name of a medicinal product containing fixed combination of telmisartan/amlodipine:	
	Amtel – the name is invented, even if created from the initial letters of the telmisartan and amlodipine INNs (less than 50% similarity with the INNs, not inconsistent with the product composition or therapeutic effects, not misleading in terms of the target patient group or the SmPC, not of promotional nature)
Unacceptable – invented name of a medicinal product containing paracetamol:	
	Parazorex – contains an INN stem –orex reserved by WHO for anorexics
	Paracet – the name has been created by simply abbreviating the INN paracetamol; greater than 50% similarity with the INN
	Paracemol – the name has been created by simple removal of one syllable from the INN, greater than 50% similarity with the INN, liable to confusion with the common name of the active substance, in this case with the INN paracetamol
	Pacetaramol – the name has been created as an anagram of the INN paracetamol, greater than 50% similarity with the INN
	Brusen – the name is liable to confusion with the name of authorised medicinal product Brufen (containing another active substance – ibuprofen)

	Topnáplast – the name is composed of two content words "top" and "**náplast**" (*patch*), which are contained in full in the name; the content word "top" may, moreover, give the impression of being promotional, and in case of a product in the form of e.g., film-coated tablets, such name would be misleading in terms of the target patient group and the SmPC
	Parababy – the name is not invented, it contains the content word "baby" and, moreover, if the product were not intended solely for paediatric population, it would give a deceitful impression with regard to the target patient group and would be contrary to the data in the SmPC
	Valsamol – for a medicinal product containing paracetamol, the name is misleading in terms of the product composition and therapeutic effects due to greater than 50% similarity with the INN valsartan, and hence it suggests the content of the active substance valsartan
Unacceptable – invented name of a medicinal product containing fixed combination of telmisartan/amlodipine:	
	Amlodel – the name is composed mostly of initial letters of the INN amlodipine (greater than 50% similarity with the INN), and, furthermore, as the product contains also active substance telmisartan, such name is not consistent with the composition and therapeutic effects of the product and is misleading in terms of the target patient group and the SmPC.

4.4. Umbrella Names

In general, umbrella names of medicinal products are the names of products of the same therapeutic group, of the same MAH, the basic invented name of which is the same and is accompanied by another part (qualifier) that sufficiently distinguishes the individual products from each other and provides the patient or healthcare professional information which will facilitate orientation and will prevent misinterpretation of the name or incorrect use of the product. The essential precondition governing the use of an umbrella name is that all products from the group in question contain at least one identical active substance and exhibit the same or similar therapeutic effect.

Basic Umbrella Name

The basic umbrella name without any qualifier should be the name of the product of the simplest composition; the qualifier together with the basic name must work as a "modular kit".

The basic umbrella name must be always separated from the qualifier with a space.

Qualifier

The qualifier in the name should express a typical property in which the product from the given group differs from all of the other medicinal products in the group.

At the same time, the qualifier in product names must be unequivocal and comprehensible for the general public. It is recommended to use qualifiers in the Czech language (in other languages only where the expression has become common on the Czech market).

With regard to potential misinterpretation of the name, qualifiers must not be composed of standalone letters and must not include non-letter characters, such as +, -, =, *, &, etc. For the same reason, the Institute prefers qualifiers in the form of at least three-character words. Nevertheless, in some cases, the use of numerals may be acceptable, e.g., for vaccines.

Qualifiers may be used also in case there is no medicinal product with the basic umbrella name without a qualifier. Nevertheless, this is possible only if the qualifier is generally known and well-established, comprehensible for the general public, and it well characterises a typical property that distinguishes the medicinal product from similar authorised medicinal products. Examples of such cases are qualifiers provided in the table below. In justified cases, however, the use of other qualifiers is also possible on the basis of assessment by the Institute.

Examples of well-established and generally acceptable qualifiers	
Qualifier:	*Specific property of the medicinal product:*
Prolong	product with prolonged-effect (such as prolonged-release tablets)
Rapid	product with quicker onset of effect (such as effervescent tablets or soft capsules)
Horký nápoj (*Hot drink*)	product intended for the preparation of oral solution, to be dissolved in hot water before use
Pro děti / Junior / Baby (*For children / Junior / Baby*)	product intended solely for the paediatric population
Pro dospělé (*For adults*)	roduct intended solely for adults
Neo / Novum	expression for a minor innovation of a medicinal product, such as active substance micronisation or product re-formulation
Pomeranč / Citron / ... (*Orange / Lemon /…*)	distinction of flavour (orange/lemon/…) of otherwise identical products
1x denně (*1x daily*)	the product is used only once a day, unlike the regular dosage of similar medicinal products
S vitaminem C (*With ascorbic acid*)	product with the addition of with ascorbic acid, if the indication of the product remains unchanged and the substance is well known to the general public [where several substances are added to the basic product, this fact has to be reflected, e.g., “s vitaminem C a kofeinem” (*with ascorbic acid and caffeine*)]
Plus / Combi / Duo	product with several active substances (qualifier “Duo” applies only to products with two active substances in total)
Forte	product of significantly higher strength
Disperg / Distab	product in the pharmaceutical form orodispersible tablets
Grip	the product contains e.g., a combination of an analgesic/antipyretic agent and phenylephrine hydrochloride and compared to the basic name, it is indicated for the treatment of flu and cold symptoms.

Each medicinal product has different properties, and for this reason, it is not possible to compile a complete list of acceptable qualifiers; qualifier suitability always depends on the properties of the specific product and on whether it sufficiently distinguishes the product of the same line or from similar authorised medicinal products.

4.5. Special Rules Governing the Content of the Name for Selected Types of Medicinal Products

Vaccines

When a new serotype is added to a vaccine containing several serotypes, this fact has 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 is to be followed in the naming of vaccines containing various types of antigens when a new type of antigen is added. New vaccines are authorised primarily via the procedure referred to in Regulation No 726/2004. This requirement complies with the NRG EMA Guideline.

Radiopharmaceuticals

In terms of name, radiopharmaceuticals are considered a special group of products, particularly due to the different method of handling thereof. With regard to the specifics of this indication group, the Institute approaches name assessment in compliance with the NRG EMA Guideline. The invented name must not contain the target organ so as to prevent the name from becoming misleading in case the indication is extended to new target organs. Furthermore, the name of a radiopharmaceutical must not contain the name or symbol of an isotope, unless it is contained in the product.

Example	
Acceptable:	
	Fluorid (18F) sodný MAH (*Sodium fluoride (18F) MAH*) – no INN exists, it is a pharmacopoeial name with the specification of the isotope number and symbol of the element in the following format: *<Radionuclide> <(isotope number and element symbol)> <ligand or carrier> <MAH>*

Homeopathic and Herbal Products

Common names of homeopathic products and herbal medicinal products may be composed of the Czech or Latin name, or by a commonly used name if there is no pharmacopoeial name, accompanied by the MAH´s name or trade mark. Instead of the Latin name, it is possible to use a name well-established in the homeopathic practice (preferred pharmacopoeial names for homeopathic products in the German Pharmacopoeia or French Pharmacopoeia, as applicable), if followed by the relevant common name of the substance, of which the product has been manufactured, in the PL and on the labelling.

Expression of strength in herbal medicinal products is assessed in compliance with the Guideline on herbal products.

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

Medicinal Gases

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 is sufficient to provide such name in the SmPC, PL and on the labelling, followed by the standard expression of the pharmaceutical form:

Medicinal gas, compressed = medicinální plyn, stlačený; Medicinal gas, cryogenic = medicinální plyn, kryogenní; Medicinal gas, liquefied = medicinální plyn, zkapalněný.

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

Active Substances Present in Various Forms

In case the active substance is present in authorised products in several forms (base, salt, ester), the Institute, in line with other EU regulatory authorities, recommends to distinguish the common names of the medicinal products containing various forms of the active substance by specifying the particular salt/form of the active substance in the name of the medicinal product.

Where the active substance is present in authorised medicinal 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.
Nevertheless, if the 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, having regard to safety in the prescription and use of the medicinal product, the Institute requires that uniformity for the market is maintained, i.e., the common name of the product containing the same active substance will be acceptable only if it contains the name of the particular salt.

Examples	
Acceptable:	
	Levocetirizine MAH – the product contains levocetirizine dihydrochloride, levocetirizine is not present in any other form in authorised products, it is not necessary to specify the particular salt in the common name
	Mycophenolate mofetil MAH – the product contains mycophenolate mofetil, products containing mycophenolate sodium with different indications have been also authorised
	Perindopril MAH – the first version of the product on the market, it contains perindopril erbumine
	Perindopril arginine MAH – the product contains perindopril arginine, it is necessary to distinguish it from previously authorised products containing perindopril erbumine that are available on the market
Not acceptable:	
	Mycophenolate MAH – the product contains mycophenolate mofetil, the name is not consistent with the names of authorised products containing mycophenolate mofetil, and is therefore misleading in terms of the composition of the medicinal product
	Perindopril MAH – for a product containing perindopril arginine, the name is misleading in terms of the composition of the medicinal product, because authorised products called Perindopril MAH contain perindopril erbumine

5. Medicinal Product Name in Braille

The name of the medicinal product for human use must be provided on the outer packaging also in Braille, unless specified otherwise in the Marketing Authorisation.

Technical parameters of Braille are governed by the EN ISO 17351 Packaging – Braille on Packaging for medicinal products (ISO 17351:2013) standard.

The outer packaging of the medicinal product must include the product name in Braille as approved by the Institute under section 16 of Labelling. The name in Braille must be provided in a manner allowing for an unequivocal identification of the medicinal product in question.

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

In the assessment of the name in Braille, upper and lower case is disregarded.

Note: If the name in Braille is followed by the expression of strength containing the units "micrograms", in justified cases (such as lack of space on the packaging), the Institute shall not insist on providing the units in full word and shall accept their expression in Braille abbreviated as "mcg". In the name provided in Braille, the Institute shall also accept simplified names of pharmaceutical forms as per Table X.

6. Preliminary Assessment of Medicinal Product Names

In case a preliminary assessment of a medicinal product name is required, the Institute shall issue a written expert opinion, the costs of expert activity will have to be reimbursed by the applicant as stipulated by Decree No 472/2008 Coll., as amended (for details, please refer to UST-29, as last amended, available on SÚKL´s website; payment code: O-002). This opinion is valid only at the time of its issuance, because the proposed name is, *inter alia,* compared to the existing names or names of medicinal products whose marketing authorisation procedure is pending. To allow for the assessment of the name, the applicant shall submit the full product name together with the application for preliminary assessment of the name, i.e., the applicant shall provide the proposed name, expected strength and pharmaceutical form as well as detailed information about the characteristics of the product for which the name is being proposed (proposed indication, target patient group, composition of the medicinal product, draft SmPC should preferably be submitted, if available to the applicant), and proof of payment of the cost reimbursement. The Institute shall consider applications without the aforementioned particulars invalid and shall request additional information meeting the aforementioned scope. A single application may contain any number of proposed names; assessment of three names for one medicinal product is adequate to one-hour work (i.e., a request for consultation with 6 proposed names will be charged as 2 hours of work, etc.).

It is recommended to submit applications for preliminary assessment of the name electronically to posta@sukl.gov.cz. Thereafter, the Institute will send the expert opinion on whether the names are acceptable or not electronically to the applicant; such opinion is valid only as at the day of its issuance and is not subject to any remedies.

7. Reporting of medication errors related to similarity of product names

The Institute calls for reporting of any medication errors, particularly in respect of those medicinal product confusions that are associated with the similarity of their names, regardless of whether such confusion occurred on the medicinal product prescription, dispensing, or use level. Reporting of cases where the health of the patient was or could have been jeopardized is of particular importance. Reports may be sent to nazvy@sukl.gov.cz and, at the same time, to farmakovigilance@sukl.gov.cz.

8. Used Terms and Abbreviations

Alphabetic list of used abbreviations:

eAF.....application form
EMA .....European Medicines Agency
INN.....International Non-proprietary Name recommended by the World Health Organisation
MA .....Marketing Authorisation

MAH.....Marketing Authorisation Holder
MR/DC .....Mutual Recognition/Decentralised Procedure
NRG.....EMA Name Review Group
PL .....Package Leaflet
® .....registered trademark
SmPC.....Summary of Product Characteristics
SÚKL, Institute .....State Institute for Drug Control
™ .....unregistered trademark

Used terms:

Holder.....Marketing Authorisation Holder
Product information.....Summary of Product Characteristics, Package Leaflet, and Labelling
Full product name .....name of the medicinal product followed by the expression of strength, incl. units, and pharmaceutical form
Table X.....Standard names of dosage forms, routes of administration and packaging