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1.1	22.04.2020	Addition to section 5.3.2.11 Name extension DOLO	sab
1.0	**01.01.2020**	**Implementation of HMV4**	**sab**

1 Definitions, terms, abbreviations

1.1 Definitions and terms

1.1.1 Medicinal product name

The medicinal product name is the proprietary name of the medicinal product

1.1.2 Core brand

The umbrella brand that links an unspecified number of medicinal product names. The core brand contains the same main name for various medicinal products of one or more marketing authorisation holders, which are then differentiated by a name extension. For medicinal products whose name consists of the name of the active substance (DCI/INN) and the company name (e.g. KAS without innovation), the company name should not be considered to be the core brand.

1.1.3 Name extension

Medicinal products that are distributed under the same core brand must be identifiable and distinguishable from each other by a name extension (prefix or suffix). The name extension combined with the main name forms a unit.

1.1.4 Suffix

Part of the name added after the main name and forming a unit with the latter.

1.1.5 Prefix

Part of the name added before the main name and forming a unit with the latter.

1.1.6 Packaging

Packaging refers to the container / pack in which the product (goods) is packed. It refers to both the primary and secondary packaging.

1.1.7 Medicinal product information, medicinal product information texts

These are considered to refer to the Information for healthcare professionals and patient information as a whole or the basic information (for export licences).

1.1.8 Dosage form

Dosage form refers to the delivery form (e.g. prefilled syringe) including the pharmaceutical form (e.g. suspension). The description of the dosage form must conform to the EDQM Standard Terms.

1.1.9 Product range

Several dosage forms with the same medicinal product name and the same qualitative active substance composition and the same indications form a product range.

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1.2 Abbreviations

TPLRO	Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the Licensing Requirements for Therapeutic Products (Therapeutic Products Licensing Requirements Ordinance, TPLRO; SR 812.212.22)
FeeO-Swissmedic	Ordinance of 14 September 2018 on the Fees charged by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic; SR 812.214.5)
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA; SR 812.21)
TPLO	Ordinance of the Swiss Agency for Therapeutic Products of 22 June 2006 on the Simplified Licensing of Therapeutic Products and the Authorisation of Therapeutic Products by the Notification Procedure (TPLO; SR 812.212.23)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (Therapeutic Products Ordinance, TPO SR 812.212.21)
No.	number
FOPH	Federal Office of Public Health
KAS	Medicinal product with known active substance(s)
DCI/INN	denominatio communis internationalis/International Nonproprietary Name

2 Introduction and objective

This guidance document describes the requirements relating to medicinal product names. As this is a guidance document aimed at administrative bodies, it does not directly specify the rights and obligations of private individuals. Swissmedic uses this document first and foremost as a resource for applying the legal provisions on authorisation in a uniform and equitable manner. The publication of the guidance document is designed to make it clear to third parties what requirements must be fulfilled according to the practice of Swissmedic.

3 Scope

This guidance document applies to the authorisation of human medicinal products. The guidance document is not applicable to complementary medicines without indication.

4 Legal framework

The TPA, the TPO and the TPLRO constitute the legal basis.

5 General requirements

5.1 Assessment principles

Article 1 paragraph 2 a TPA states that the purpose of the act is to protect consumers of therapeutic products against fraud.

Based on Article 9 paragraph 4 TPO, a medicinal product name is rejected if it is contrary to public order or decency, could be misleading or lead to mix-ups.

In line with long-standing Swissmedic practice, Article 9 paragraph 4 TPO is interpreted to mean that medicinal product names are rejected if they are not objectionable from the health policy standpoint. This may in particular be the case if, due to the choice of product name,

1st confusion with other medicinal products is possible,
2nd the composition / quality, effect / efficacy or risks / safety of the medicinal product can be wrongly assessed, or

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3rd the improper consumption of the medicinal product is promoted.

In terms of its typeface ("look alike"), sound ("sound alike") or significance in respect of possible associations or logically related concepts, the medicinal product name should allow adequate differentiation and an appropriate assessment of the medicinal product.

Swissmedic assesses medicinal product names based on therapeutic products legislation. Aspects of trademark protection fall within the remit of private law and are therefore not covered by therapeutic products legislation. This has the following consequences:

- The fact that a medicinal product name is legally protected as a trademark is not relevant for the evaluation by Swissmedic. Consequently, an applicant cannot assert its right to a medicinal product by referring to trademark law (under which the product name is a registered trademark).
- Therefore, Swissmedic is not responsible for dealing with trademark claims among distributors.

The medicinal product names are checked during the review of the authorisation application or the application for a change to the product name. In specific individual cases, preliminary clarification can be obtained in the context of a Presubmission Meeting (see guidance document *Meetings for applicants held with the Authorisation sector HMV4*). Reserving a medicinal product name is not possible.

5.1.1 Preconditions for a company name and abbreviations as part of the medicinal product name

The medicinal product name should be unique, clear and unambiguous, and therefore not confusable, and may not include references to non-approved indications or pharmacologically incorrect statements or permit interpretations.

Previously merged marketing authorisation holders, companies that otherwise have an existing or historical connection with the medicinal product (manufacturer, marketing authorisation holder) and even any other arbitrary companies that are, or were, not involved in the distribution of manufacture of the relevant preparation, can be part of the medicinal product name.

Two different marketing authorisation holders can use the same company name as a part of the medicinal product name, even if the company name involves just one of the two authorisation holders.

The name of the marketing authorisation holder can be used in abbreviated form. Mere single letters or sequences of letters that could be confusing or misleading and that are not identifiable as an abbreviation of the name of the authorisation holder must be explained with a footnote.

Active substance abbreviations are not permitted unless they are generally known and self-explanatory.

5.1.2 Medicinal product names for KAS

The name of a KAS can consist of a creative name or the name of the active substance (name according to DCI/INN) or else a descriptive name – e.g. company XY hay fever, film-coated tablets – combined with a company name.

For a KAS without innovation, the preferred option is the selection of a medicinal product name consisting of the active substance name according to DCI/INN combined with the company name.

5.1.2.1 Medicinal product names for generics with new excipients

If, in connection with a variation application (new medicinal product with same active substance but with a new excipient formula, new manufacturer or manufacturing process), a new authorisation

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procedure with a new authorisation number is required, the existing medicinal product can be retained, provided all the following requirements are satisfied:

- The medicinal product is reformulated in respect of the excipients (excipient formula), but the pharmaceutical form remains the same (e.g. does not apply if a film-coated tablet is changed to an orodispersible tablet)

and

- The medicinal product name consists of the name of the active substance (name according to DCI/INN) and the company name (therefore does not apply to brand name or creative names)

and

- The active substance does not have a narrow therapeutic index (to be substantiated by the authorisation holder).

During a transitional period of at least 6 months from the granting of the authorisation, the following bilingual (D/F), clearly visible and clearly legible statement should be printed on the folding carton: "Gleicher Wirkstoff – Neue Hilfsstoffe" / "Même principe actif – nouveaux excipients" ["Same active substance – New excipients"]. Alternatively, the new feature ("New excipients") can be mentioned first.

During a transitional phase of a maximum of 6 months from the granting of authorisation for the "new" medicinal product, the "old" medicinal product may continue to be on the market at the same time with the same medicinal product name.

For the old formula, and before the new medicinal product is authorised, distribution must either cease from DDMMYY (max. 6 months after authorisation of the new medicinal product) or an application for variation of the medicinal product name must be submitted by the end of the transitional period.

If an application for variation of the medicinal product name is submitted for the "old" medicinal product, the following should be observed: An addition such as "N", "Neo", "Novo", "Novum", "New formula" to the existing medicinal product name is not possible, since this suggests a change to the active substance composition that has not occurred.

Professionals should be informed in an appropriate form before the product is placed on the market. An appropriate form, for example, would be a circular to professionals, the fast online publication of the Information for healthcare professionals, publication in the "Schweizerische Ärztezeitung" or "Pharmajournal" or, if applicable, "Drogistenstern". If desired, this information can optionally be provided via "Pharmavista" (Industry News). The following information must be included: The date from when the new formula will be available, the new authorisation number and packaging code, the modified excipients and, if applicable, the changed appearance (form, colour, inscription of the unit dose).

5.1.3 Reactivation of a deleted medicinal product name after revocation of the authorisation

The name of a medicinal product whose authorisation has been revoked can be used for a different medicinal product 5 years after deletion at the earliest.

Exception: An exception is made if the medicinal products do not differ significantly (or at all) in respect of the active substance composition and indications. If applicable, a name extension may be needed.

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5.2 Preconditions for a core brand

Medicinal products within the same core brand are usually distributed by the same marketing authorisation holder. The individual medicinal products under a core brand may be distributed by different marketing authorisation holders.

Basically, all medicinal products that are distributed under the same core brand must be provided with a specific name extension such that the medicinal products can be identified and clearly differentiated from each other by their name.

Exception:
If a core brand is only created subsequently by the notification of a new medicinal product (medicinal product name with name extension) in relation to an existing authorised medicinal product (medicinal product name without name extension), the addition of a name extension to the existing authorised medicinal product may be omitted in justified individual cases: the applicant must prove that the health risk in the event of confusion of the core brand partners due to the missing extension is negligible.

5.2.1 Examples of medicinal product groups that are suitable for core brands

The use of a core brand is possible in particular for:

- prescription-only and/or non-prescription medicinal products (monopreparations with the same active substance, including different salts, methods of administration and pharmaceutical forms / dosage forms, dosage strengths) with closely related, but not identical, indications;
- medicinal products with different active substance compositions but with related, strictly limited, indications;
- fixed medicinal product combinations with pure substances isolated from plants, medicinal product combinations containing synthesised or partially synthesised active substances from plant-based raw materials in addition to genuine plant-based active substances, and genuine phytotherapeutic products;
- medical devices and medicinal products;
  Note: Swissmedic checks the names of ready-to-use medicinal products. Since the names of medical devices are not checked by Swissmedic, the marketing authorisation holder is responsible for avoiding any possible risk of confusion with medical devices.
- Medicinal products and preparations that are subject to control by the FOPH (cosmetics, nutritional supplements, disinfectants, etc.), provided the areas of application are related.
  Note: Swissmedic checks the names of ready-to-use medicinal products. The names of preparations that are subject to control by the FOPH (cosmetics, nutritional supplements, disinfectants, etc.) are not checked by Swissmedic. The marketing authorisation holder is therefore responsible for avoiding any possible risk of confusion with products subject to FOPH control.

5.3 Preconditions for a name extension

Name extensions are an integral part of the medicinal product name. The same preconditions apply, i.e. a name extension must not be contrary to public order or decency, potentially misleading or likely to lead to mix-ups.

Name extensions can be placed before (prefix) or after (suffix) the main name.

The core brand and the name extension must appear on packaging materials and in the product information as a unit (i.e. name extension in a font size at least half as large as the core brand).

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Name extensions must be clear, unambiguous and, particularly for non-prescription medicinal products, sufficiently understandable and transparent for laypeople.

5.3.1 Unacceptable name extensions

Name extensions may not be of a promotional nature. Therefore, name extensions such as "SUPER ONE DAILY", "PERFORMANCE", "NEW INDICATION", "SPONTANEOUS", "BOOST", "RECORD", "REPAIR" or "TREND" are unacceptable.

Name extensions that potentially suggest a non-existent difference between the individual medicinal products are not acceptable, e.g. "DOUBLE ACTION", "FORMULA 1", "FLASH".

Name extensions may not suggest associations with food products, beverages, tobacco products or utility articles and thus potentially lead to trivialisation of a therapeutic product e.g. "BIO", "NATURA", "COMFORT", "STICK", "INSTANT", "EXPRESS", "ACTIVE".

Negative declarations of excipients as additions to the medicinal product name are not permitted (e.g. without gluten/gluten-free, without lactose/lactose-free, without preservatives, without gelatine/gelatine-free, without flavourings/flavouring-free, without fragrance, without alcohol/alcohol-free, without sugar/sugar-free, without bisulphite, CFC-free).

This list of unacceptable name extensions is not exhaustive.

5.3.2 Examples of name extensions

5.3.2.1 Acute and similar

Preconditions for the name extension ACUTE:

- The medicinal product is indicated exclusively for the treatment of medically relevant acute conditions

and

- A medicinal product with the same active substance and indicated for the treatment of chronic conditions is already authorised or notified.

5.3.2.2 Chrono and similar

Preconditions for the name extension CHRONO:

- An oral or parenteral dosage form is involved

and

- After administration, the product is absorbed immediately, regularly and for a prolonged period.

5.3.2.3 Direct and similar

Preconditions for the name extension DIRECT:

- A solid oral dosage form is involved

and

- The medicinal product may be taken without fluid (water)

and

- A medicinal product with the same active substance and to be taken with fluid (water) is already authorised or notified.

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5.3.2.4 Uno and similar

Preconditions for the name extension UNO:

- A reference medicinal product with the same product name and whose active substance is also contained in the medicinal product to receive the name extension UNO must be authorised or notified.

and

- The name extension UNO refers to the dosage instruction. In contrast with the reference medicinal product, the preparation is used only once a day or once a week.

5.3.2.5 Duo, Trio and similar

Preconditions for the name extension DUO, TRIO:

- A reference medicinal product with the same product name and whose active substance is also contained in the medicinal product to receive the name extension DUO must be authorised or notified.

and

- The name extension DUO refers to the dosage instruction. In contrast with the reference medicinal product, the preparation is used twice a day.

or

  - DUO in the sense of composite, i.e. the preparation contains two active substances. *(although the suffix COMPOSITE would be better here).*
  - DUO in the sense of forte, i.e. the medicinal product contains only one active substance, but its dose is double that of the reference preparation. *(although the suffix FORTE would be better here).*
  - DUO in the sense of a medicinal product combination with two active substances that complement each other.

5.3.2.6 Forte, Plus, Extra and similar

Preconditions for the name extension FORTE, PLUS, EXTRA:

- A reference medicinal product with the same product name and with similar indications and whose active substance is also contained in the medicinal product to receive the name extension (e.g. FORTE, PLUS or EXTRA) must be authorised or notified.

and

- The medicinal product with the suffix (e.g. FORTE, PLUS or EXTRA) differs from the reference medicinal product in terms of a modified active substance composition that has been shown to lead to increased efficacy or safety during use. This is the case, for example, if the medicinal product with the extension (e.g. FORTE, PLUS or EXTRA) contains one or more additional active substances or higher active substance doses.

5.3.2.7 N, NEO, NOVO, NOVUM, New formula, New formulation and similar

Precondition for the name extension N, NEO, NOVO, NOVUM, NEW FORMULA, NEW FORMULATION:

- The medicinal product is reformulated in respect of its active substances (elimination, replacement, addition or change in quantity).

After the end of a period of at least 5 years, the extension can be omitted. To this end, an application to change the name of the medicinal product should be submitted to Swissmedic.

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If the active substance composition of a medicinal product is changed repeatedly at short intervals, Swissmedic may, for reasons of transparency or safety, demand an extension to the name of the medicinal product other than "new formulation", or even a change to the medicinal product name itself.

5.3.2.8 Rapid and similar

Precondition for the name extension RAPID:

- It must have been demonstrated that the medicinal product has a faster onset of effect than a comparator product with the same main name and the same active substance (different salt/enantiomer is possible)

and

- Studies proving clinical-therapeutic relevance in respect of the faster onset of effect must be submitted.

5.3.2.9 Retard, SR (slow release), CR (controlled release), IR (immediate release) and similar

Precondition for the name extensions Retard, SR (slow release), CR (controlled release), IR (immediate release):

- Studies proving clinical-therapeutic relevance in respect of the delayed onset of effect must be submitted

and

- The abbreviations (e.g. SR, CR, IR) are explained in the medicinal product information.

5.3.2.10 Indication (e.g. hay fever, coughs and colds etc.)

Precondition for the indication as a name extension:

- The indication as a name extension corresponds to the indication in the medicinal product information

and

- No other indications may be listed in the medicinal product information

and

- The authorised indications may not be marketed separately and individually under several medicinal product names (e.g. with name extensions "migraine pain", "headache", "joint pain", etc.)

and

- The same medicinal product may not be marketed in multiple forms under the same core brand (e.g. as basic product with name extension "thyme tea" and as a co-marketing medicinal product with the name extension "cough tea")

5.3.2.11 DOLO

Precondition for the name extension DOLO:

- A reference medicinal product must be authorised with the same product name and with similar indications as the medicinal product which is to receive the name extension DOLO

and

- The medicinal product with the suffix DOLO is authorised for the short-term treatment of acute pain without a medical prescription.

5.4 Time limits

The time limits are based on the guidance document *Time limits for authorisation applications HMV4*.

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5.5 Fees

The fees specified in the Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic) apply.

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