Dear Sir or Madam,

Today we would like to provide further information on the topic “New guideline on the naming of medicinal products”.

We are at your disposal, should you require assistance or have further questions.

Best regards

The DiaMed Team

NEW GUIDELINE ON THE NAMING OF MEDICINAL PRODUCTS PUBLISHED

BfArM and PEI have published a new version (version 8.1) of the "*Guideline of the Federal Institute for Drugs and Medical Devices and the Paul Ehrlich Institute on the naming of medicinal products*", which will be applied from 15 August 2023 on.

The order of chapters in the document has been fundamentally changed; it is now more structured and better comprehensible. The term "extended name of the medicinal product" (name plus strength plus pharmaceutical form, as well as information on the group of users, if required) has been removed; instead, it is described that in addition to the name - which, as before, can be an invented name or a generic name - the elements strength, pharmaceutical form and, if applicable, group of users should be included. What is new here is mentioning that unless it is mentioned in the name itself, this information *must* follow the name as labelling elements according to Section 10 AMG. The nomenclature thus is much clearer and better explained.

New is some clear guidance on the spelling:

- Permissible letters: The German alphabet plus umlauts and ß
- Upper and lower case:
- The upper and lower case should be used according to German use; the initial letter should be capitalised, the rest of the word in lower case.
- The use of capital letters only should be avoided.
- Capital letters within a word may only be used in justified cases.
- A superscript or subscript (example: "name^{x}"; "name$_{n}$") is not permitted.
- Numbers are not allowed outside of strength (in contrast, their use was previously possible if they were understood as a reference to a dosage instruction such as "1 time daily" - whether this will actually be rejected by the authority in future remains to be seen).

The requirement to avoid single or double letters (previous version: "letter sequences") outside of established medical or pharmaceutical abbreviations was already present in the previous version.

However, care must be taken when implementing an already accepted name: Despite the objections of the pharmaceutical associations, BfArM clearly states in the new version that an approved name including the approved upper and lower case spelling must be implemented in an exactly matching manner and any change needs to be approved by a variation procedure.

Forbidden spelling is now also more clearly defined, the following is inadmissible:

- Mathematical operators (such as plus sign or minus sign)
- Punctuation marks such as semicolon, exclamation mark
- Special characters, such as @ or #

On the other hand, slashes or hyphens may be permissible if they are used, for example, as separators for active substances. However, they are to be avoided as a connection of individual letters with words (outside of INN).

In the case of trademarks, the visual reference to the trademark protection is permitted in the printed version, but they are not included in the marketing authorisation letter.

Use of trademarks/umbrella brand names

As many pharmaceutical entrepreneurs have experienced for themselves in recent years, the authorities have relaxed their attitude towards the use of umbrella brand names. This is also reflected in the new version of the guideline. It is still clear that an umbrella brand name must not be misleading and must not lead to confusion or deception of users.

However, a less strict approach is now taken with the use of an umbrella brand name for medicinal products with different active ingredients. This was previously to be "avoided". The wording has been deleted; but the requirement remains that the use of an umbrella brand name for different active substances must be examined on a case-by-case basis and the risk of confusion, and the resulting consequences must be well weighed up.

This also includes that, according to the new version of the guideline, a qualifier (suffix) must be added to the umbrella brand name used, preferably by specifying the active ingredient that is sufficiently distinct from the original name (of the other medicinal product of the umbrella brand).

Generic drug names
In the generic drug names, it has been newly included that combinations of active ingredients are to be separated by a slash (a "+" is not permitted). For new combinations, the order is to be indicated according to the alphanumeric order of the WHO classification for the ATC code (or according to the reference medicinal product).

Indication of strength
It was also newly included that the strength must also be included for herbal and traditional medicinal products as well as for vitamin and mineral preparations. This obligation was not previously stated in the guideline.

List of possible qualifiers
Of course, the authorities point out that the list of possible qualifiers, which is included in the annex in both versions, is not exhaustive and the use of one of the suffixes is subject to a case-by-case assessment. Nevertheless, the list provides a good indication for pharmaceutical entrepreneurs who would like to use a qualifier.

The following changes were made to the list:

These qualifiers are no longer listed:
- Elixier („elixir“)
- pure
- Tonikum („tonic“)
- TTS (Transdermal Therapeutic System)

These possible qualifiers are new:
- direkt (“direct”, for solid dosage forms for immediate oral intake without liquid; not applicable to drops, oral sprays, orodispersible tablets and lozenges, etc.).
- junior (should be supplemented by a specific age statement)
- liquid (for medicinal products in single-dose containers, direct intake without further liquid)
- ohne Konservierungsstoffe (“without preservatives”; the possible qualifier "sine" is also retained)
- protect (protective effect, e.g. for heart and/or stomach, if the active substance is available on the market in a different strength and/or indication).
- depot (the possible qualifier "retard" is also retained)

These qualifiers have been adapted:
- akut (“acute”): now also for narcotics, in order to distinguish normal-release medicinal products from prolonged-release medicinal products.
- forte: new: in addition to the higher dosage, the product must have a proven stronger effect
- mit <Geschmacks- oder Geruchskorrigentien> (“with <flavour or odour-correcting agents>”: in addition to the reference to aromas (e.g. mit Zitronenaroma, "with lemon aroma"), "with" may now also be used for flavours (e.g. mit Zitronengeschmack, "with lemon flavour"), however, "-flavour" or "-aroma" must always be included (applies in particular to honey aroma).

- mono/uno: with the new version it was specified that these qualifiers are preferably to be used to differentiate a medicinal product from a product from the same manufacturer with the same and another active substance (--> "duo")

Overall, the new version of the guideline is clearer and offers more detailed instructions in many areas, which cannot all be presented here. Therefore, when choosing a name for a medicinal product, consultation of the guideline is essential; the summary presented here can only provide an overview of the major changes.

The admissibility of a name cannot be requested from the authority in advance. It is possible, though, to have a potential name assessed by the authority in the context of a Scientific Advice (subject to charge).