Owner/responsible party:
Product Information Working Group

CBG MEB

MEDICINES EVALUATION BOARD

Policy document

Nomenclature of pharmaceutical products

MEB 13

November 2024

Owner/responsible party:

Product Information Working Group

Contents

1 Introduction

This policy document, MEB 13: Nomenclature of pharmaceutical products, applies to all product names established by the Medicines Evaluation Board (MEB). These are the product names of all medicinal products for which the MEB issues (parallel) marketing authorisations.

This document describes the requirements a marketing authorisation holder has to fulfil when submitting a product-name proposal for a pharmaceutical product.

European guidelines on the nomenclature of pharmaceutical products are set out in Directive 2001/83/EC. These requirements are implemented in the Dutch Medicines Act (*Geneesmiddelenwet*).

The name of the medicinal product and product name
The definition for the name of a medicinal product is set out in the Dutch Medicines Act: it is an invented name or a common or scientific name (INN) accompanied by a brand or the name of the marketing authorisation holder.

According to Directive 2001/83/EC, the strength and pharmaceutical form are not part of the **name of the medicinal product**. However, the strength and pharmaceutical form must be included in Section 1 of the SmPC, Label Text and Package Leaflet in accordance with the SmPC Guideline, Readability Guideline and the QRD template.
The full name of the medicinal product, followed by its strength and pharmaceutical form, is also expressed in the marketing authorisation, under the name of the medicinal product.

Product name
In this document, the term “product name” is used to indicate the full name of the medicinal product, followed by its strength and pharmaceutical form.

For the purpose of the product-name assessment, it is important to read and apply this nomenclature policy document together with labelling policy (MEB 6: Labelling of pharmaceutical products).

The documents published by the EMA’s Working Group on Quality Review of Documents (QRD) provide more information on the identification of a product in the summary of product characteristics, in the package leaflet and on the packaging.

The EMA Name Review Group coordinates the nomenclature of products that have been or are to be authorised via the centralised procedure. See the document entitled 'Guideline on the acceptability of invented names for human medicinal products processed through the centralised procedure' for the guidelines on the nomenclature of centralised products.

1.1 Other documents relevant to the nomenclature of pharmaceutical products

Other policy documents about the nomenclature of pharmaceutical products:

Via WHO

- **The use of common stems in the selection of International Non-proprietary Names (INN) for pharmaceutical substances. (WHO/EDM/QSM/99.6)**
  This document provides guidance on the use of the INNs for pharmaceutical substances in the nomenclatures of medicinal products.
  who-pharm-s-nom-1570.pdf

Via EMA

- **Guideline on the acceptability of invented names for human medicinal products processed through the centralised procedure (EMA/CHMP/287710/2014 (Rev 6))**
  Acceptance criteria that the CHMP has formulated for the names of pharmaceutical products that are processed through the centralised procedure.
  Guideline on the acceptability of names for human medicinal products processed through the centralised procedure - Scientific guideline | European Medicines Agency (europa.eu)
- **QRD Recommendations on the expression of strength in the name of centrally authorised human medicinal products (as stated in section 1 of SPC, and in the name section of labelling and PL)** (EMA document Doc. Ref. EMA/707229/2009).
  quality-review-documents-recommendations-expression-strength-name-centrally-authorised-human_en.pdf (europa.eu)

Via CMD

- CMDh Best Practice Guide on Multilingual Labelling (CMDh/413/2019) and the internal CMDh document with instructions for RMS/CMS (CMDh/441/2022)
  CMDh_413_2019_Rev3_2021_10_clean_CMDh_BPG_on_multilingual_packaging.pdf (hma.eu)

Via MEB website

- MEB 5: Package leaflet of pharmaceutical products
- MEB 6: Labelling of pharmaceutical products
- MEB 21: Statement of 'abbreviated indications' on packaging of OTC products

Via Wetten.Overheid.nl https://wetten.overheid.nl/zoeken

- Dutch Medicines Act
- Medicines Act Regulation

2 Basic principles of nomenclature

The product name is one of the most important points of recognition for healthcare professionals and users.

The product name is part of the assessment of the dossier and is assessed based on the potential risk of medication errors. Previously taking decisions on product names cannot, by definition, be used as a reason to accept a new product name.. This is assessed on a case-by-case basis.

The MEB takes the following into account:

a) Product name in the Dutch language

Labelling information, including the product name, must be in the official language of the Member State where the product is to be marketed. If an INN name is used, the national translation of the INN name must be used in each country. All translations of these INN names are deemed to be the same established INN name.

b) Name confusion

The product name should not cause confusion with the name of another authorised pharmaceutical product or with other active substances. T. This applies to the name when it is printed, handwritten or pronounced.. The use of repeated vowels or consonants and special characters can make product names difficult to pronounce. Names that are difficult to pronounce may be rejected as this may cause confusion and make it difficult to recognise a medicinal product.

In addition, the MEB considers the following aspects when assessing a product name:

1. If an invented name is used, no confusion may arise with the general or scientific name. Neither may any confusion arise about the product's composition.
2. The name should not result in any misunderstanding regarding the product's therapeutic or pharmaceutical characteristics.
3. The similarities and differences in the method of administration between the product and products that have already been authorised;
4. The similarities and differences in legal status of supply (e.g. prescription (UR) or over-the-counter (UA, UAD or AV)) between the product and products that have already been authorised.

In principle, product names may not be used more than once, with the exception of line extensions (see Section 8.2).

Exceptions to this rule are assessed on a case-by-case basis. The following conditions are taken into account:

- No confusion must be possible between the product and historical products;
- The original product is no longer authorised and not on the market anymore.

When an authorisation has been deleted, a period of five years must have elapsed, in principle, before the likelihood of confusion through the re-use of a product name is deemed negligible.

For generics, the exception described in Section 3.1.3 applies.

The MEB requires a sufficient difference between the pronunciation and spelling of the names of different pharmaceutical products. Therefore the name of one product must differ by at least three letters (or characters). The MEB may always require more of a difference between names, if it deems necessary. This will be assessed on a case-by-case basis.

c) Not for promotional purposes

An invented name may not convey a promotional message. Product names (including any additions) that have a promotional aspect are not acceptable. This means that any promotional aspect of the name of the marketing authorisation holder, or any promotional aspect of an abbreviation that refers to the name of the marketing authorisation holder, must not be included in the product name.

The MEB recognises that there is a thin line between promotional and informative. In general, the MEB is very reluctant to approve product names of a potentially promotional nature.

The product name may not include direct or indirect references to (a recommendation by) scientists or healthcare professionals. In this context, healthcare professionals include doctors, pharmacists, drugstore employees, midwives, nurses and dentists. An indirect reference may consist of the expression of matters closely associated with them (Rod of Aesculapius), a reference to the institution at which they work (university, clinic, institute, laboratory, pharmacy, drugstore, etc.) or the type of work they perform (research, diagnoses).

d) Policy on previously-approved product names

If the name of an authorised product no longer meets current nomenclature requirements, the company may be made aware of this in a procedure. The company is not required to change the product name immediately, unless this would be in the interests of public health.

3 Generic product name or invented name

3.1 Generic product name

A generic product name must always start with the substance name. The reason for this is that pharmacists and other professionals would find it more difficult to search databases if all product names started with the name of the marketing authorisation holder. This requirement does not apply to umbrella brands (see Section 6). The MEB does not impose any other requirements on the order applicable in generic names.

The brand or the name of the marketing authorisation holder may not be omitted from a generic product name. In other words, it is not permitted to express just the common or scientific (INN) name of the substance as the name of the medicinal product.

The three-letter (character) difference rule may be waived in some cases for generic product names (see Section 3.1.2 below).

Common or scientific name (INN)

The general or scientific name is the generic name (INN name) recommended by the World Health Organisation. If an INN name exists for a particular substance, it must be used exactly as published, without any omissions or abbreviations. All translations of these INN names are

considered equal to the internationally approved INN name. If there is no INN name, the name may be chosen in line with the European Pharmacopoeia, BAN (British Approved Name) or USAN (United States Adopted Name). Vitamin analogues are an exception to this rule, as the general nomenclature for vitamins is more recognisable to consumers than the INN name.

Example: Paracetamol Marketing authorisation holder or Brand name 500 mg, tablets
This name is **permitted**. It is an INN to which the name of the marketing authorisation holder or a brand has been added.

3.1.1 Salt form and esters

For the nomenclature of products with the same composition, the sequence of the product name of the individual components, the salt form and any strength indication and pharmaceutical form must be used consistently.If the general or scientific name is used, the active substance must be stated first, followed by the salt, unless the WHO stipulates otherwise.The innovator, reference product or the first representative will always determine the order to be used. The same applies to combination products, e.g. Augmentin (amoxicillin/clavulanic acid). It is important to maintain a consistent policy for this in order to avoid confusion..

Example: Potassium losartan Marketing authorisation holder or Brand name 50 mg, tablets
This name is **not permitted**. The base must be mentioned first, followed by the salt - unless the WHO specifies otherwise. However, the following *is* permitted: Losartan potassium Marketing authorisation holder or Brand name 50 mg, tablets.

A salt or ester form must only be expressed in the name if it has a pharmacological effect. If the salt or ester form is not included in the name, it must be stated close to the product name on the packaging, as stated in the policy document MEB 6: Labelling of pharmaceutical products. This option is not possible if other salt or ester forms have been authorised previously. In that case a distinction must be made between the different salt forms on the basis of the product name..

If the name of an innovator does include the strength of the salt or ester, the generics will follow this to avoid any confusion in practice.

If the strength of the pharmacologically-active substance is not declared in the name, the quantitative information must be expressed in SmPC section 2, for example.

Each film-coated tablet contains 10 mg abiraterone acetate equivalent to x mg abiraterone

Example for Acebutolol

Acebutolol Marketing authorisation holder or Brand name 200 mg tablets
Acebutolol
This name is **permitted**. The number '200 mg' in the name corresponds to the actual situation. However, the product information must still express that the HCl salt has been included ('one tablet contains acebutolol-HCl corresponding to 200 mg acebutolol').

Example for Perindopril (innovator Coversyl 2 mg)

Perindopril Marketing authorisation holder or Brand name 2 mg tablets
perindopril tert-butylamine
This name is **permitted**. Preferably, the reference to the active substance will correspond to the strength expressed in the name. The product actually contains 2 mg perindopril tert-butylamine and not 2 mg perindopril base. Even though the first line of the name suggests that 2 mg of base is present, this name *is* permitted. Expressing the salt form in full in the product name is correct, in principle. However, this is not necessary in many cases, as it has no impact on the therapeutic effect. Inclusion of the salt form in the product name also makes the product name unnecessarily long. The MEB prefers to avoid this situation. However, the salt form must be statedclose to the product name on the packaging, as stated in MEB 6: Labelling of pharmaceutical products).

Perindopril tertbutylamine Marketing authorisation holder or brand name 2 mg tablets
perindopril tert-butylamine
This name is **permitted**. The name is declared in the salt form because, in this case, the company has registered multiple salts of the same base. To be able to differentiate between them, the preferred option is to include the salt in the product name.

Therefore, in situations such as in the case of products containing perindopril tert-butylamine, it is preferable to opt for an invented name.

Perindopril Marketing authorisation holder or brand name 1,6789 mg tablets
perindopril (as tert-butylamine salt)
This name is **not permitted**. The conversion to the amount of base results in an undesirable decimal fraction in the strength indication. In addition, the relationship to the innovator strength becomes unclear.

Example for Amlodipine

Amlodipine (as maleate) Marketing authorisation holder or brand name 5 mg tablets
amlodipine
This name is **permitted**, provided the incorporation of the maleate compound ('one tablet contains amlodipine maleate corresponding to 5 mg amlodipine') is expressed elsewhere on the packaging (and in the SmPC and package leaflet).

If the marketing authorisation holder does not wish to use the name in the example above, it can opt for an invented name, as in the case of the innovator product

Invented name 5 mg tablets
amlodipine malate corresponding to 5 mg amlodipine
This name is **permitted**, but the compound used cannot now be deduced directly from the name.

3.1.2 Name of the marketing authorisation holder

The name of the marketing authorisation holder may not give rise to confusion; nor may it be of a promotional nature. Therefore, numbers and abbreviations that could give rise to confusion are not permitted (also see Section 7.6). If the name of the marketing authorisation holder is used in the name of a medicinal product, it must correspond to the full name, or part of the name, of the marketing authorisation holder. A marketing authorisation holder may use multiple different names, provided other authorisation holders are not using these names and they are not being used as brands.

In a generic product name in which the INN name is followed by the name of the marketing authorisation holder, the three-letter (character) difference rule no longer applies to the names of the marketing authorisation holders. If there is a difference of at least one character between the name of the marketing authorisation holder in a new generic INN product name

and the name of a marketing authorisation holder in a generic INN product name that has already been authorised, the former name will be acceptable.

If the name of the marketing authorisation holder is not used in the name of the medicinal product, the name of the manufacturer, company or holder of a brand may be used; this is then deemed to be a 'brand'. A brand name may not refer to a company that is acting as a marketing authorisation holder of other products. This could give rise to confusion about which party is responsible for marketing the product.

However, the marketing authorisation holder may be a different legal entity to the holder of the brand (naturally, agreements will have been made between them in this situation). Several marketing authorisation holders may use the same brand in the names of their products subject to the conditions above. If the holder of the brand is going to act as the marketing authorisation holder as well, the brand name and name of the authorisation holder may not coexist as elements of the names of the medicinal products. The same applies when one marketing authorisation takes over another marketing authorisation holder.

The name INN + company/brand name Y is permitted if company Y is a marketing authorisation holder and Y is not used as a brand name by another marketing authorisation holder.

This name is also permitted if company A (itself a marketing authorisation holder) is the holder of brand Y and no company Y exists that is a marketing authorisation holder.

If, in the second situation, company Y now also wants to market Product Company Y as a marketing authorisation holder, this will not be permitted because confusion could then arise as to which party is responsible for the product. The potential confusion stems from the fact that it is impossible to infer from the product name whether the addition Y refers to brand Y or marketing authorisation holder Y. In this situation, Company A and Company Y will need to determine which of them is able to continue to use the addition Y in the product name.

If one marketing authorisation holder takes over another marketing authorisation holder, the name of the medicinal product may continue to include the company name of the company that has been taken over (Company X), while the company that has taken over Company X (Company Y; which is a marketing authorisation holder too) acts as the marketing authorisation holder for the products of Company X. However legal entity X may not also continue to hold authorisations with the name of Company X in the name of the medicinal product. The same

applies to a foreign parent company that operates as an authorisation holder and has a Dutch subsidiary that acts as a contact address or distributor.

Example: Brand name Paracetamol 500 mg Marketing authorisation holder tablets
This name is **not permitted**. The combination of the name of the brand and the marketing authorisation holder is confusing in terms of the identity of the party responsible for marketing the product. A choice must be made between the brand or the name of the marketing authorisation holder.

Example: Pardolica Manufacturer's name 500 mg tablets
This name is **permitted**, provided the manufacturer is not the marketing authorisation holder of other products in the Netherlands. In this example, the manufacturer's name effectively constitutes a 'brand'.

Example: Marketing authorisation holder / brand name Paracetamol 500 mg tablets
This name is **permitted in specific situations**. The company is marketing a number of over-the-counter medicinal products that contain the brand name in their name. Therefore, in this case, the name of the company is a brand that accompanies the common/scientific name (paracetamol). This can result in the creation of an umbrella brand (see Section 6).

Example: Paracetamol Subsidiary Company 500 mg tablets
This name is **permitted**. The subsidiary is a distributor of the parent company's products in the Netherlands. The parent company owns the subsidiary. The subsidiary itself is not acting as the marketing authorisation holder of other products. The name of the subsidiary can effectively be deemed to be a 'brand'. This is not permitted if the subsidiary itself is acting as the marketing authorisation holder for a number of other products.

3.1.3 Identical generic product names

A marketing authorisation holder can apply for an identical generic product name (INN + MAH or brand) for a number of generic products (even if they are not copies) subject to certain conditions.

This is only permitted if the following two conditions are met:

- Both products are bioequivalent to the same reference product (in the case of generics with a legal basis of Section 10.1), or therapeutically equivalent (in the case of hybrid products with a legal basis of Section 10.3);
- The products do not differ in an excipient mentioned in the excipients guideline (e.g. if one product contains lactose and the other does not, the names may not be the same).

If generic and hybrid medicinal products have been authorised for different indications, the differences between them, e.g. a difference in strength and/or pharmaceutical form, must be expressed in the product name and on the packaging. This is assessed on a case-by-case basis.

The names of biosimilars with a legal basis of Section 10.4 and fixed dose combinations with a legal basis of 10b may not be identical.

When distinguishing between generic and hybrid medicinal products, it is not sufficient to repeat the pharmaceutical form in the product name before the strength or to change the order of the pharmaceutical form and strength in the product name.

Example

Clobazam Marketing authorisation holder or brand name 10 mg, tablets is permitted

Clobazam Marketing authorisation holder or brand name tablet 10 mg, tablets as an alternative name is not permitted

3.1.4 Generics of centrally-authorised products

A condition for a generic product of an innovator product authorised via a centralised procedure is that the product name must be the same in all member states where the product application has been submitted, regardless of the procedure that has been applied for the authorisation of the product (MRP, DCP, CP, RUP). In accordance with Directive 2001/83/EC, the name of a product can be either an invented name or a general or scientific name in combination with the name of the marketing authorisation holder or the (umbrella) brand. The general recommendations for product names should be observed in this regard.The following exceptions apply to the condition above:

- A deviation from the proposed product name in one of the member states is permitted, if the proposed name is rejected or an appeal is lodged against the proposed name

based on the trademark law in that member state. This must be demonstrated in sufficient detail.

- A deviation from the proposed product name in one of the member states is permitted, if the marketing authorisation holder is not the same in each member state and the marketing authorisation holder does not control the (umbrella) brand in one or more countries. Proof must be submitted to show that the marketing authorisation holder does not own the (umbrella) brand.

3.2 Invented names

When an invented name is used, it may not contain an INN stem (at the beginning, in the middle and/or at the end).

INN stems which are used for certain class of active substances can be found in Annex 3 of the 'Guideline on the Use of International Non-proprietary Names (INNs) for Pharmaceutical Substances' of the World Health Organization (WHO). This guideline states that 'to avoid confusion, which could jeopardize the safety of patients, trade-marks cannot be derived from INNs and, in particular, must not include their common stems'.The WHO guideline above is used to avoid potential confusion between invented names and active substances, based on the Dutch translation of the INN stem.

The name of the marketing authorisation holder or a brand may be included in the product name, if this product name is an invented name. The name of the marketing authorisation holder or brand that is mentioned in the product name may be regarded as part of the 'invented' element.The combination of the invented name and the name of the marketing authorisation holder (or brand) may not result in a so-called 'umbrella brand' in the name. Additional conditions apply in this situation. See Section 6, ´Umbrella brands´.

Example: Pardolica Marketing authorisation holder 500 mg, tablets
This name is **permitted**, the expression of the name of the marketing authorisation holder in the invented name above may be deemed to be part of the 'invented' element.

The use of one or more capital letters in the middle of the name is not recommended. Neither is it recommended to write the entire product name in capital letters. However, the MEB does not object to this in principle.

4 Strength and pharmaceutical form

4.1 The expression of strength

The MEB has a strong preference for the inclusion of a strength in the product name. If the strength is not part of the product name, this information must always be stated elsewhere on the most important side of the packaging. For example, in the case of tablets: 'one tablet contains X mg Y', with Y being the active substance. More information about the expression of this information on the packaging can be found in policy document MEB 6: Labelling of pharmaceutical products.

The strength must always be followed by the strength unit.

Information about the correct expression of strength in the product name for various pharmaceutical forms can be found in the 'QRD Recommendations on the expression of strength in the name of centrally authorised human medicinal products' on the EMA website.

4.1.1 Specific conditions when expressing strength

- When expressing strength, the type of compound (salt or ester) in which the active substance is present must be taken into account; see Section 3.1.1. According to the QRD recommendations mentioned above, any reference to the active substance on the packaging must always correspond with the strength. In many cases, it is not necessary to express the salt or ester form in the product name in full. However, it is currently mandatory to declare the strength in accordance with the base, if the active substance is actually the base. An exception to this rule applies if the innovator is declared based on the salt or ester. In this case, generics should follow the strength of the innovator (also see Section 3.1.1).
- The strength of the medicinal product must be expressed as the quantity of active substance per unit of dosage, volume or weight, depending on the pharmaceutical form. A space must always be included between the strength and the unit.
- The ‘µ’ symbol, as used to indicate micrograms, may not be used, as this could cause confusion. Added to this, the strength indication ‘micrograms’ must be written in full and not in the abbreviated for (mcg) to avoid confusion with milligrams.
- In principle, it is no longer permitted to express a concentration as a percentage. However, this is still permitted in the name of those products in which the concentration determines

the effect more than the total amount and for which it has been common practice to express the strength in percentages for some time. For example, sodium chloride 0.9 %.

If products neutralise heparin, "antiheparin IE/ml" may be included in the name. Here, antiheparin refers to the strength listing, not the indication.

4.2 Expressing the pharmaceutical form

The European Directorate for the Quality of Medicines and Healthcare (EDQM) has determined how the full pharmaceutical form is to be expressed. It has decided that the use of a patient-friendly term for the pharmaceutical form is not permitted in the product name.

The EDQM uses a certain word order for some pharmaceutical forms, to group related terms alphabetically; e.g. 'Capsule, hard' and 'Capsule, soft'. If one of these forms is expressed in the product name, the pharmaceutical form in the product name must be amended to an expression in correct Dutch. For example: 'hard capsules' or 'soft capsules'.

5 Differences in legal status of supply

It is not possible to register two products with the same active substance and strength but with a different legal status of supply (over-the-counter and on prescription) under the same product name. The reason for this is that there will then be a substantial difference in both dossiers, e.g. a difference in therapeutic indications, dosage and/or contraindication. This is because, by definition, an over-the-counter product does not have the same indication as a prescription product.

Over-the-counter medical products can be subdivided into UA, UAD or AV, e.g. on the basis of packaging size. These generally fall under the same authorisation, meaning that the same product name can be used given the absence of any substantial difference between the dossiers.

If a change in legal status of supply results in a change to the product name, the product name must be sufficiently distinct to avoid any confusion with the original product. In the event of a change from OTC to PO, the indication in the name may no longer be used for this purpose (see Section 7.3).

6 Umbrella brands in the name

An umbrella brand is a shared brand for a group of over-the-counter medicinal products. The umbrella brand increases the consumer's familiarity with the products as a group. These products may differ in terms of composition, active substances, pharmaceutical form and therapeutic indications.

The product name starts with the name of the umbrella brand, e.g. Kruidvat Ibuprofen 200 mg, coated tablets

For umbrella brands the name of the active substance must be included in the product name. The reason for this policy is that, in practice, the product names of a series of products from one umbrella line can be so similar that the mention of the active substance alone does not distinguish the products sufficiently. The only exception to the requirement of stating the active substance is when a unique invented name is linked to the umbrella brand, meaning that the entire name is linked exclusively to that single product. The product names must not give rise to any misunderstanding in terms of efficacy for the indications specified or, where the composition is concerned, in terms of active substances.

The use of indications in the name is no longer permitted for names with an umbrella brand either, unless the situation described in Section 7.3 applies. If there are several products within one umbrella line that have the same active substance, but different indications, the MEB stipulates that the abbreviated indication should be stated on the primary side of the packaging. This is the side on which the trade name is stated. A list of abbreviated indications is available (policy document MEB 21: Statement of 'abbreviated indications' on packaging of OTC products). Lastly the MEB expresses a strong preference to include the strength in the name as well.

Umbrella brands should also avoid creating confusion about who is responsible for marketing the product. A company that uses the umbrella brand as its company name may not act as the marketing authorisation holder for other products (also see Section 3.1.2). However, an umbrella brand can have a number of marketing authorisation holders.

Of course, the name of the umbrella brand and the marketing authorisation holder may indeed correspond for the product itself. In actual fact, the 'name of the marketing authorisation holder in the name' is the case in the latter situation, which is permitted.

7 Additions or characteristics

7.1 General

Special additions to the generic name or invented name are limited by the relevant regulations. However, it may be desirable to express more information so that the type of product is clear to the healthcare provider and patient or in situations where the patient chooses which product to use based on the packaging (e.g. over-the-counter products). For that reason, the MEB is prepared, in a number of cases, to permit different additions on the packaging to those permitted in law. This is only possible if the conditions in this section are fulfilled.

If higher or lower strengths are released to or removed from the market, this can have consequences for additions or previously approved products names. Depending on the situation, additions may have to be removed or amended.

7.2 An addition for different formulations

If different formulations of a medicinal product are available, it is important to determine whether the INN name alone is sufficient to distinguish between the various products. In some situations, the INN name alone does not distinguish sufficiently, for example in the case of lipid complexes.

In these cases, one of the options below must be selected:

- Use an invented name;
- An addition to the name (qualifier), e.g. "liposomal", "liposomal formulation".

Qualifiers are additions to the product name that provide more specific information about the product and, as such, express the distinction between the product names of similar medicinal products.

Example: Amphotericin B lipid complexes
These products all have the same substance name but contain different lipid complexes. If there are different formulations of innovators with the same active substance, an addition to the name will be necessary.

Generics	Innovators

Amfotericine B	Fungizone
Amphotericin B colloidal	Amphocil
Amphotericin B lipid complex	Abelcet 5 mg/ml lipid complex
Amphotericin B liposomal	Ambisome liposomal amphotericin B

Examples:

Paclitaxel albumin Marketing authorisation holder

Paclitaxel NAB Marketing authorisation holder

These names are not permitted.
Albumin and NAB (Nanoparticle Albumin-Bound) may not be added to INN Paclitaxel as a qualifier because albumin is not a component of the active substance but a vehicle (carrier) of the active substance.

Where a different dosage applies for a product (different to standard use, e.g. use once a week and not every day), it is possible to differentiate in the name by including the dosage, e.g. “for once-daily dosing". This is assessed on a case-by-case basis.

7.3 The addition of indications

For over-the-counter medicinal products there is the option to include a so-called 'abbreviated indication' (or additional information about the area of application) elsewhere on the packaging. See policy document MEB 21: Statement of ‘abbreviated Indications’ on packaging of OTC products for the relevant criteria. A request to add an abbreviated indication to this list can be submitted to the MEB.

In the case of over-the-counter products, it is possible to include a reference to the indication in the product name subject to the following conditions:

- The abbreviated indication must be one of those set out in policy document MEB 21: Statement of ‘abbreviated indications’ on packaging of OTC products.

- The indication must always be expressed in combination with the pharmaceutical form (i.e. throat tablets or antacid capsules; not an antacid).

Although an invented name should generally be a name without general meaning, the MEB does not object if there is a certain correlation between the invented name and the application. Of course, this correlation should not be misleading and this will be assessed on a case-by-case basis. A name like Imigran (for migraines) is acceptable in this context.

For products that neutralise heparin, "antiheparin IE/ml" may be included in the name. Here, antiheparin refers to the strength listing, not the indication.

7.4 An addition for special age groups

The MEB only considers it desirable to refer to the age group in the product name when a number of pharmaceutical forms and/or strengths have been authorised for a medicinal product and are intended for different age groups. This policy prevents a situation where the addition ‘adults’ has to be expressed in the name of all products for which no research has been carried out on children, for example.

However, if a pharmaceutical product is intended exclusively for use by a certain age group, a precise indication of the age group in question (e.g. 'for children aged 1 to 8 years') may not be included in the product name. A less precise indication of the age group, e.g. 'for children' or 'junior', *may* be included in the product name, provided the precise age group is clearly defined elsewhere on the packaging. Also see policy document MEB 6: Labelling of pharmaceutical products.

7.5 Additions for pro-drugs or derivatives

If the active substance is a pro-drug or is derived from a previously authorised active substance, the use of an existing name with the addition of a prefix or suffix (for example, the prefix 'pro') is not permitted. If a product is considered to be a new active substance, a different product name should be selected for this product than the approved product name for the original active substance (also see Section 7.7).

7.6 The addition of abbreviations and numbers

The MEB prefers not to use abbreviations. The MEB will not allow an abbreviation if it can result in confusion with abbreviations that have a pharmaceutical or scientific meaning (for example, SC, HP, IU, IM, CR).

The use of numbers in the name of a product, other than as part of the strength, might result in confusion about the strength and the administration instructions and is therefore not permitted. Neither are numbers permitted as part of the marketing authorisation holder's name. The above does not apply in the event of the functional addition of a combination of numbers and letters that have been commonplace for a long time and are indispensable to the avoidance of confusion, as is the case with vitamins (e.g. Vitamin D3).

7.7 Other additions

The MEB may permit additions that do not sound Dutch but are considered to be very commonplace. Such additions must comply with the additional conditions below:

- The foreign term should not be a replacement for the information that, according to the Medicines Act, must be included on the packaging (in Dutch). In this case the foreign term in the product name is merely supplementary to the information which, on account of the above-mentioned statutory obligation, should automatically appear on the packaging (in Dutch). This will not have any detrimental effect on a reader who does not speak a foreign language. Information in another language can be acceptable on the condition that this information is also stated in Dutch on the packaging due to the obligation to state in accordance with the Medicines Act.
- The use of a foreign term in the product name may not cause confusion.

For example, the term ‘liquid caps’ is considered sufficiently commonplace and, as such, is permitted in the product name.

Permitted additions:

Addition	Specific details

'sugar-free' 'gluten-free' 'no preservative' 'CFC-free'	These terms are permitted. Other similar expressions that indicate that a product is free of certain substances are not permitted.
dash or hyphen (-)	Permitted.
symbol ® or ™	Permitted in the name when expressing the name on the packaging and in the package information leaflet. The addition of these symbols is not permitted in the Summary of Product Characteristics. See the document by the European level working party 'Quality Review of Documents' (QRD). Therefore, these symbols will not be expressed on the marketing authorisation.
'Kit' 'Combination package'	Permitted.

Permitted subject to specific conditions:

'Forte' 'Mitis' 'Extra' 'Extra strong'	Permitted, provided the strength is included in the name in quantitative terms. The MAH must also have gained authorisation for multiple strengths of the same active substance. It is not permitted to use these additions as a claim to highlight certain characteristics. Therefore, it is not permitted to indicate the strength in qualitative terms alone.
'cardio'	'cardio' was allowed in the past because of its practical application. This addition is now only permitted in combination with acetylsalicylic acid.

'retard' 'CR'	Permitted, provided it characterises the release profile of the pharmaceutical form.
'IV' 'IM' 'SC'	Permitted, provided it indicates the route of administration.
'Plus'	Additions to indicate that the product is a combination of two or more active substances are permitted, provided both substances are mentioned in the name. 'Plus' as a claim to highlight certain characteristics is not permitted (see below).
'with citrus flavour', 'menthol', 'mint', 'spearmint' etc.	Permitted, provided that it is in accordance with the composition of the product and that it relates to a neutral description of the flavour. (Taste) sensations 'Hot', 'Cool', 'Cool Mint', 'coolmint', 'Fresh', 'Fresh Mint', 'freshmint', etc. are not permitted because these are deemed to be promotional.
'Easyhaler', 'Clickhaler', 'Turbohaler', 'Autohaler'	Permitted, provided they relate to the inhaler device itself. Additions relating to the pharmacology of the product are not permitted.

Not permitted:

Addition	**Specific details**
'Instant', 'Quick'	Not permitted because 'instant' and 'quick' can be interpreted in different ways such as fast-acting or for immediate use. This can cause confusion.

‘Combi’ ‘Comp’	Not permitted because it may suggest both a combination product and a combination packaging. ‘Kit’ or ‘Combination package’ *is* permitted for combination packages.
‘Co-’ ‘-Plus’	The addition of ‘Co-’ and ‘plus’ to a name (e.g. Co-X and X plus) are not permitted for combination products if one of the active substances in the combination product has also been marketed in singular form under the name X. Even if a generic wishes to market the relevant combination product and has not marketed the singular product, the addition of the name 'Co-' or 'Plus' is not permitted. ‘Plus’ is only permitted if both substances are mentioned in the name.
Pro-	Not permitted for pro-drugs and/or derivatives of existing products (see Section 7.5).

8 Special products and situations

8.1 Combination package and combination products

8.1.1 Combination package

A combination package is a package that contains more than one medicinal product and is marketed under a single trade name and has a single marketing authorisation. The qualitative or quantitative compositions of the individual products are different and they are administered at the same time or sequentially.

The strengths of the individual products must be included in the name of combination packages. The MEB has a strong preference for the expression of the pharmaceutical form in the name for combination packages. If both products have the same pharmaceutical form, it is not necessary to repeat the pharmaceutical form. However, all pharmaceutical forms must be mentioned in the event of different pharmaceutical forms. In this situation, the strengths of the active substances must be separated by the word ‘and’ or the plus sign (‘+’) in the product

name. To avoid confusion with combination products, the slash sign (‘/’) may not be used in combination packaging. The name of the combination product alone must be expressed on the outer packaging. The name of the combination product must also expressed on the individual components; the substance name contained in the individual component must follow underneath it.

Example: RiseCaD 35 mg film-coated tablets and 500 mg/880 IU effervescent granulate

Full product name on combination package:
RiseCaD 35 mg film-coated tablets and 500 mg/880 IU effervescent granulate

Primary packaging of the individual components:
RiseCaD
Sodium risedronate 35 mg, film-coated tablets

RiseCaD
Calcium/holecalcifero 500 mg/880 IU, effervescent granulate

8.1.2 Combination product

A combination product is a product that contains a combination of active substance in one and the same pharmaceutical form. The name of a combination product must differ sufficiently from the names of the individual active substances and product names of other combination products.

As stated above, the MEB strongly prefers the inclusion of the strength(s) in the name if the product contains one or two active substances. This preference does not apply in the event of three or more active substances.

A full invented name must be used for combination products or, if reference is made to the active substances, a reference to each of the substances applicable must be included. The strength order must correspond to the active substances referred to in the product name. In the product name, the different strengths and the different active substances present in one combination product are separated from each other by a slash sign (‘/’), unless this adversely affects the legibility of the product name.

Example: eye drops

Latanoprost/Timolol Marketing authorisation holder 50 micrograms/ml + 5 mg/ml, eye drops, solution

This name is permitted.
If the different strengths are also separated by a slash instead of a plus sign, the product name will be difficult to read.

Example: Calci-kit D3 500 mg/800IE/70mg
This name is **not permitted**. As evident from its strength, this product contains three active substances, namely alendronic acid with calcium and vitamin D3. The product name does clearly refer to the calcium and vitamin D3, but not to the alendronic acid, which is the main ingredient in the preparation.

Example: Alenca D3 70 mg/500 mg/800IE
This name is **permitted**, this product refers to all three active substances, namely alendronic acid, calcium and vitamin D3. The order of the strength expressions must correspond to the order of the active substances referred to in the name.

8.2 Line extensions

In the case of a line extension, the product name must be the same as the name used for the previously authorised medicinal product. The difference between both products is expressed in the product name (thus, the same name plus the relevant addition, different pharmaceutical form and/or different strength).

8.3 Parallel import

The MEB prefers the same name as the Dutch reference product to be used in a parallel marketing authorisation in order to limit the risk of confusion. If the Dutch reference product has a name that is not yet in line with the current nomenclature document, this might result in a conflicting situation. In that case the MEB will tolerate a name that is not in line with the current nomenclature document.

8.4 Vaccines

If a new serotype is added to vaccines that consist of different serotypes, the original invented name may be retained. In this situation, the name of the vaccine must be followed by the number of serotypes present and the pharmaceutical form. The description of serotypes is expressed in the qualitative and quantitative composition, e.g.:

Invented name X serotypes suspension for injection.

The same applies when different antigens are added to an existing product. This is particularly important if both vaccines are available on the market simultaneously, so that it is possible to distinguish between the two products.

8.5 Biologicals

If changes are made to the production of a biological (e.g. line extensions) that result in a new form of the product that replaces the old form, the decision on continued use of the existing product name is made on a case-by-case basis. If the characteristics of a particular product have changed (e.g. by adding an adjuvant), a name change may be necessary.

8.6 Radiopharmaceuticals

Radiopharmaceuticals are subject to the rules applicable to the Dutch product name. However, in very exceptional cases, the MEB may decide not to require use of the Dutch language on the label where radiopharmaceuticals are concerned.

9 Abbreviations and definitions

INN	International Nonproprietary Names for Pharmaceutical Substances
MAH	Marketing Authorisation Holder
MEB	Medicines Evaluation Board English translation of the College ter Beoordeling van Geneesmiddelen
QRD	Quality Review of Documents

Owner/responsible party:

Product Information Working Group

SmPC	Summary of Product Characteristics
WHO	World Health Organisation