

Policy document MEB 13
Nomenclature of pharmaceutical products

MEB 13
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1. Table of contents

1. Table of contents.....	2
2. Abbreviations and definitions	3
3. Introduction	3
4. General policy.....	4
5. Invented name or generic name	6
5.1. Invented names	6
5.2. Generic product names	7
5.3. Name of the marketing authorisation holder	9
5.4. Identical product names	10
6. Umbrella brands in the name	11
7. Differences in legal status of supply	12
8. Strength and pharmaceutical form	12
9. Additions or characteristics.....	15
9.1. The indication	15
9.2. Special age groups	16
9.3. Use of prefixes and suffixes	16
9.4. Abbreviations and numbers	16
9.5. Other additions.....	16
10. Special products/situations	18
10.1. Combination packages and combination products.....	18
10.2. Line extensions	19
10.3. Generics of centrally authorised products	19
10.4. Parallel import	20
10.5. Vaccines	20
10.6. Biologicals	21
10.7. Radiofarmaca.....	21
11. Related documents.....	21

2. Abbreviations and definitions

INN	International Nonproprietary Names for Pharmaceutical Substances
MEB	Medicines Evaluation Board
QRD	Quality Review of Documents
SmPC	Summary of Product Characteristics
WHO	World Health Organisation
OTC	Over-the-counter medicinal products

3. Introduction

This policy document, MEB 13 The nomenclature of pharmaceutical products, is applicable to all product names which the Medicines Evaluation Board (MEB) determines. These are the product names of all medicinal products for which the MEB issues a (parallel import) marketing authorisation.

This document describes the requirements which the marketing authorisation holder has to fulfil when submitting a proposal for a product name for a pharmaceutical product. The European guidelines for the nomenclature of pharmaceutical products can be found in Directive 2001/83/EC. These requirements have been incorporated into the Dutch Medicines Act [Nederlandse Geneesmiddelenwet].

The definition for the name of a medicinal product can be found in the Medicines Act:

Product name: 'Name of a medicinal product, consisting of an invented name or a general/scientific name, accompanied by a brand or the name of the marketing authorisation holder, possibly supplemented with strength and pharmaceutical form.'

Nomenclature: 'The product name, if necessary* followed by the strength, pharmaceutical form and, if necessary, the active substance. This provides a set of distinguishing characteristics on the packaging.'

*According to Directive 2001/83/EC, it is not compulsory to state the strength and pharmaceutical form in the **product name**. However, the strength, pharmaceutical form and active substance must be included in the **nomenclature**. If the pharmaceutical form and strength are already part of the product name, it is not necessary to repeat them.

For the assessment of the nomenclature it is important to read and apply this policy document about the nomenclature together with the policy for labelling (MEB 6: Labelling of pharmaceutical products).

The documents by the European 'Quality Review of Documents' (QRD) working party provide more information about the identification of a product in the summary of product characteristics, in the package leaflet and on the packaging.

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

4. General policy

When naming medicinal products, a distinction is made between product name and nomenclature in order to avoid (excessively) long product names.

The **product name** is the name of a medicinal product, consisting of an invented name or a general/scientific name, together with a brand or the name of the marketing authorisation holder (generic product name), possibly supplemented with strength and pharmaceutical form. The product name is always stated before the comma, for example: Paracetamol Marketing Authorisation Holder 500 mg, tablets. The **nomenclature** is the product name of the medicinal product, if necessary together with the strength, pharmaceutical form and, if necessary, the active substance.

According to Directive 2001/83/EC, it is not compulsory to state the strength and pharmaceutical form in the **product name**. However, the strength, pharmaceutical form and active substance must be included in the **nomenclature**. If the pharmaceutical form and strength already are part of the product name, they do not have to be repeated after the comma.

The brand or the name of the marketing authorisation holder must not be omitted in the case of a generic product name. In other words, it is not permitted only to state the general or scientific (INN) name of the substance. It is no longer possible to use these so-called 'preparation names'. The term 'register name' (product name before the comma; pharmaceutical form and strength after the comma) has been replaced by the term 'nomenclature'.

A generic product name must always start with the substance name. The reason for this is that it is more difficult for pharmacists and other healthcare professionals to search in the registers if all product names start, for example, with the same name of the marketing authorisation holder. However, the above does not apply to invented names (see section 5.1) and umbrella brands (see section 6). The MEB does not impose any additional requirements, other than those referred to above, on the sequence of the marketing authorisation holder, strength and pharmaceutical form.

The nomenclature on the packaging is the most important point for recognition and identification and it should be prominently visible on the packaging. All other information is subordinate to this. The nomenclature can be spread across several lines on the packaging and, if necessary, in different font sizes. However, a condition is that the reader sees the nomenclature as a single whole.

Basic principles of nomenclature

The product name is part of the assessment of the dossier and is assessed based on the potential risk of medication errors. Each product name is assessed on the basis of the currently applicable policy. 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. When doing so the MEB takes account of the following:

Product name in Dutch

Details for the labelling, including the nomenclature of the medicinal product, must be drafted in the official language of the member state in which the product is to be marketed. This is evidenced by the reference in Article 63, 1st paragraph of Directive 2001/83/EC, which refers to Articles 54, 59 and 62 of that same Directive (Article 54 under a relates to the name of the medicinal product). 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 considered to be equal to the same established INN name.

No name confusion

The product name should not cause confusion with the name of another authorised pharmaceutical product or with other active substances. This applies to the name when it is printed, handwritten or pronounced.

The MEB requires that there is sufficient differentiation in the pronunciation and notation of the product name for different pharmaceutical products. Therefore, the product names must differ by at least three letters (characters). The MEB can always request a more extensive difference between product names, if it considers such to be necessary. This will be assessed on a case by case basis.

In the case of generic product names, it is possible, in some cases, to deviate from the three letters (characters) difference rule (see section 5.3 below).

When doing so the following aspects should be taken into consideration:

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/differences in the method of administration.

4. The similarities/differences in legal status of supply (for example on prescription (UR) or non-prescription (UA, UAD or AV)).

Not for promotional purposes

An invented name is not allowed to convey a promotional message. Product names (including any additions) that have a promotional aspect are not acceptable.

This means that it is not acceptable to include any promotional aspect in the name of the marketing authorisation holder in the product name or any promotional aspect in an abbreviation that refers to the name of the marketing authorisation holder.

The MEB acknowledges that there is a thin line between promotional and informative and in general the MEB is very reticent about approving any potentially promotional product names.

Names of medicinal products may not directly or indirectly refer 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 can consist of a reference to matters closely associated with them (Rod of Aesculapius), a reference to the institution they work at (university, clinic, institute, laboratory, pharmacy, drugstore, etc.) or the type of work they perform (research, diagnoses).

Policy on previously approved product names

If a name of an authorised product no longer meets the current nomenclature requirements, the company can be informed about this during a procedure. However, the company is not required to change the name with immediate effect, unless this is in the interest of public health.

5. Invented name or generic name

5.1. Invented names

When an invented name is used, the name should not end with a letter combination that is used by the World Health Organization as INN stem for a certain class of active substances. 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 MEB uses this WHO guideline as guidance for the use of INN stems in the case of invented names in order to avoid potential confusion between invented names and active substances. In this context the basis is 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 such cases. See section 6 entitled 'Umbrella brands'.

Example: Pardolica Marketing Authorisation Holder 500 mg, tablets

This name is **permitted**. The use of the marketing authorisation holder's name can be considered as part of the 'invented' element of the above-mentioned invented name.

The use of a capital letter in the middle of a word seems contrived and is not recommended. Neither is it advisable to display the entire product name in capital letters. However, the MEB does not object to this in principle.

5.2. Generic product names

General or scientific name (INN)

The general or scientific name is the general name (INN name) recommended by the World Health Organization. If an INN name exists for a specific substance, this must be used exactly as published, without omissions or abbreviations. All translations of these INN names are also considered to be equal to the internationally approved INN name. In the absence of an INN name, the name can be selected in accordance with the European Pharmacopoeia, BAN (British Approved Name) or USAN (United States Adopted Name). An exception are the vitamin analogues, because the general nomenclature for vitamins is more recognisable to the consumer than the INN name.

Example: Paracetamol Marketing Authorisation Holder or Brand Name 500 mg, tablets

This name is **permitted**. It is a general/scientific name to which the name of the marketing authorisation holder or a brand has been added.

Salt form and combination products

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, the reference product, or the first representative always determines the sequence. The same applies to combination products, such as augmentin

(amoxicillin/clavulanic acid) or co-trimoxazole (trimethoprim and sulphamethoxazole). 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 should be mentioned first and then the salt, unless the WHO stipulates otherwise. The following is, however, permitted: Losartan potassium Marketing Authorisation Holder or Brand Name 50 mg, tablets

It is, in principle, correct to state the salt form in full in the product name, although it is unnecessary in many cases because the salt has no influence on the therapeutic effect. In addition, the product name becomes unnecessarily long if the salt form is included. Consequently, this is not the preference of the MEB. A condition is that the salt form must be stated near the product name on the packaging, as stated in the MEB 6 policy document: Labelling of pharmaceutical products (see also the examples in section 8). This option is not possible if others salt or ester forms were previously registered. In that case a distinction must be made between the different salt forms on the basis of the product name.

Different formulations

For generic medicinal products where the innovator consists of various formulations, 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 following options must be selected:

- Name of the generic medicinal product: the company can opt for either an invented name, or an addition to the name (for example liposomal).
- Additional information on the packaging: This must be assessed on a case-by-case basis, but examples include: 'for once daily dosing' or 'liposomal formulation'.

Example: Amphotericin B lipid complexes

These products all have the same substance name, but contain different lipid complexes. If various innovator formulations with the same active substance are in use, a description of the formulation must be added to the name of a generic medicinal product to ensure that it is sufficiently distinguishable.

Generics	Innovator
Amphotericin B	Fungizone
Amphotericin B colloidal	Amphocil
Amphotericin B lipid complex	Abelcet
Amphotericin B liposomal	Ambisome

5.3. Name of the marketing authorisation holder

The name of the marketing authorisation holder may not lead to confusion and may not be promotional. Numbers and abbreviations that may result in confusion are therefore not permitted (see also section 9.4). If the name of the marketing authorisation holder is used in the product name, it must correspond to the full name or a part of the name of the marketing authorisation holder. A marketing authorisation holder is allowed to use several different names, provided these names are not being used by other marketing authorisation holders or used as brands.

In the case of a generic product name in which the INN name is followed by the name of the marketing authorisation holder, the names of the marketing authorisation holders no longer have to differ from each other by at least three letters (characters). If the name of the marketing authorisation holder in a new generic INN product name differs by at least a single character from the name of a marketing authorisation holder in a previously registered generic INN product name, this 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 and this will be regarded as a 'brand'. A brand name may not refer to a company which is itself acting as a marketing authorisation holder of other products. This could result in confusion about who is responsible for marketing the product.

However, the marketing authorisation holder can be a different legal entity to the brand name holder (although they will, of course, have reached an agreement on the matter). Several marketing authorisation holders may use the same brand in their product's name, subject to the conditions referred to above. If the holder of the brand is itself going to act as marketing authorisation holder, the brand name and the name of the authorisation holder may not coexist as elements of the product names. The same also applies in the event of a takeover between two marketing authorisation holders.

The name INN + company/brand name Y is permitted if company Y is the marketing authorisation holder and Y is not being used as a brand name by a different 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 which is itself 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 may arise about who is responsible for the product. As it cannot be deduced from the product name whether the addition Y refers to the brand Y or to the marketing authorisation holder Y. In this case it is up to Company A and Company Y to determine between each other who can continue to use the addition Y in the product name.

In the event of a takeover between two marketing authorisation holders, the company name of company X that has been taken over may still be used in the product name, whilst company Y that has taken over the other company (and is also acting as marketing authorisation holder) will now act as marketing authorisation holder for the products of company X. This is on the condition that legal entity X does not itself still hold authorisations with the name of company X in the product name. The same also applies to international mother companies that operate as licence holder and have a Dutch subsidiary company that acts as a contact address or distributor.

Example: Company (brand) name Paracetamol 500 mg* Marketing authorisation holder tablets

This name is **not permitted**. A combination of a brand and a marketing authorisation holder causes confusion in terms of who is responsible for marketing the product. A choice must be made between either a brand, or the name of the marketing authorisation holder.

Example: Pardolica Manufacturer's name 500 mg tablets

This name is **permitted**, provided that the manufacturer does not act as a marketing authorisation holder for other products in the Netherlands. The manufacturer's name effectively forms a 'brand'.

Example: Company (brand) name Paracetamol 500 mg tablets

This name is **permitted in specific situations**. The company markets a number of over-the-counter products that express the brand name. In this case the company's name is, therefore, a brand that accompanies the general/scientific name (paracetamol). This can result in an umbrella brand (see section 6).

Example: Paracetamol Subsidiary company 500 mg tablets

This name is **permitted**. The subsidiary company acts as distributor of the mother company's products in the Netherlands. The mother company owns the subsidiary company. The subsidiary company does not act as marketing authorisation holder for other products. In fact, the subsidiary company's name can be considered a 'brand'. However, this is not permitted if the subsidiary itself acts as a marketing authorisation holder for a number of other products.

5.4 Identical product names

Generic product names

A marketing authorisation holder can apply for an identical generic product name for several generic products (even if they are not a copy). This is permitted on the condition that the composition of both products is qualitatively and quantitatively similar and that both products are bioequivalent with the same reference product (in the case of generics with a legal basis of 10.1), or are therapeutically equivalent (in the case of hybrid products with a

legal basis of 10.3) and therefore interchangeable. In the event that both products differ in terms of an excipient which is referred to in the guideline of excipients, the two product names are not allowed to be identical.

If such generic and hybrid medicinal products have been registered for different indications, the mutual differences, such as the difference in strength and/or pharmaceutical form, must be expressed in the product name and/or on the packaging. This is assessed on a case-by-case basis. If these conditions are met, the style of the mock-up can be the same in that case.

Invented names

In the case of invented names, the general rule is that product names should differ sufficiently to avoid confusion between names. In general, an invented name may not be used multiple times, with the exception of line extensions (see section 10.2). However, in exceptional cases, an invented name may be reused in order to use the brand familiarity of the product. This is assessed on a case-by-case basis. A condition is that:

- there must be no confusion regarding historical products, and
- the original product is no longer authorised and is no longer on the market.

6. Umbrella brands in the name

An umbrella brand is a shared brand for a group of over-the-counter (OTC) 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.

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 nomenclature of the products should not result in any to misunderstanding with regard to the efficacy for the listed indications or in terms of the composition, with regard to the active substances.

The use of indications in the name is no longer permitted for names with an umbrella brand either, except for the situation described in section 9.1. 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 (MEB 21 policy document: 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 company name may not act as marketing authorisation holder for other products (see also section 5.3). Of course, the name of the umbrella brand and the marketing authorisation holder may indeed correspond for the product itself. In fact, the latter is a case of 'name of the marketing authorisation holder in the product name', which is permitted.

7. Differences in legal status of supply

It is not possible to register two products with a difference 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 the two dossiers, for example a difference in therapeutic indications, dosage and/or contraindication. By definition, an over-the-counter product does not have the same indication as a prescription product.

Over-the-counter medicinal products can be subdivided into UA, UAD or AV, for example on the basis of the packaging sizes. These generally fall under the same authorisation, meaning that the same product name can be used because there is no substantial difference between the dossiers.

If a change in the legal status of supply results in a change to the name, the name must be sufficiently distinct so that it cannot be confused with the original product. In the event of a change from OTC to 'Prescription Only' the indication may no longer be used in the name for this purpose (see section 9.1).

8. Strength and pharmaceutical form

It is not compulsory to state the strength and pharmaceutical form in the product name. However, the strength and pharmaceutical form must always be part of the nomenclature.

Strength

If the strength is included in the product name, it does not have to be stated again on the packaging 'following the product name'. However, 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 stating these details on the packaging can be found in MEB 6 policy document: Labelling of pharmaceutical products.

If a strength without a strength unit has been accepted in the product name, the number will have to be restated separately in the nomenclature in combination with the strength unit.

Information about the correct stating of the strength in the 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.

Specific conditions for stating the strength

- When stating the strength, the type of compound (salt/ester) in which the active substance is present must be taken into consideration. According to the above mentioned QRD Directive, any reference to the active substance on the packaging should always correspond to the strength. In many cases it is unnecessary to state the salt form in full in the product name. However, it is currently compulsory to declare the strength according to the base, if the active substance is actually the base. An exception to this is if the innovator is declared in the salt form, in which case generic products should follow the innovator strength.
- The strength of the medicinal product is expressed as the quantity of active substance per unit of dosage, volume or weight, depending on the pharmaceutical form.
- The symbol ' μ ', as used to indicate micrograms, may not be used as this sign can cause confusion.
- In principle it is no longer permitted to state the concentration as a percentage. However, for those products where the concentration has a greater impact on the effect than the total amount and where stating the strength in percentages has been common practice for some time, it is still acceptable to state percentages in the name, for example sodium chloride 0.9 %.

Pharmaceutical form

The EDQM has laid down how the full pharmaceutical form must be stated. Two different terms should not be stated on one packaging. This can cause confusion, for example in the event of specific release profiles. Therefore, the use of a patient-friendly term for the pharmaceutical form is not permitted in the product name. The EDQM does have an option for indexing several pharmaceutical forms, for example: capsules, soft. In these cases, the pharmaceutical form in the product name must be amended to a correct presentation, i.e.: soft capsules.

Example of 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, it must be stated elsewhere on the packaging (and also in the summary of product characteristics and in the package leaflet) that the HCl salt has been incorporated ('one tablet contains acebutolol-HCl equivalent to 200 mg acebutolol'). (see section 5.2)

Example Perindopril (innovator Coversyl 2 mg)

Perindopril Marketing authorisation holder or brand name 2 mg tablets

perindopril tert-butylamine

This name is **permitted**. The reference to the active substance must preferably correspond to the strength as expressed in the name. The product actually contains 2 mg perindopril

tert-butylamine and not 2 mg perindopril base. Although the name in the first sentence suggests that 2 mg of base is present, this name is permitted. It is, in principle, correct to state the salt form in full in the product name, although it is unnecessary in many cases because the salt has no influence on the therapeutic effect. In addition, inclusion of the salt form in the product name makes the product name unnecessarily long. This is not the preference of the MEB. A condition is that the salt form must be stated near the product name on the packaging, as stated in the MEB 6: Labelling of pharmaceutical products (see section 5.2).

**Perindopril tert-butylamine 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 several different salts of the same base. In order to distinguish between these forms, it is permitted to include the salt in the product name. For the sake of completeness, it is not acceptable here to convert to the quantity of base, as this would result in a decimal fraction in the strength indication and the relationship with the innovator strength would also become unclear. 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 Amlodipine

**Amlodipine (as maleate) Marketing authorisation holder or brand name 5 mg tablets
amlodipine**

This name is **permitted**. A condition is that it must be stated elsewhere on the packaging (and also in the summary of product characteristics and in the package leaflet) that the maleate compound has been incorporated ('one tablet contains amlodipine maleate equivalent to 5 mg amlodipine').

Invented name 5 mg tablets

amlodipine maleate equivalent to 5 mg amlodipine

This name is **permitted**. If the marketing authorisation holder does not wish to use the above-mentioned nomenclature, an invented name can be used, as for the innovator product. This means that the compound used can now no longer be deduced directly from the name. In those cases where the same marketing authorisation holder has registered products with different compounds of amlodipine, an additional clarification on the second line is deemed essential.

9. Additions or characteristics

Special additions to the invented name or the general or scientific name are limited by the regulations. It can still be desirable to provide more information because patients themselves choose to use the product on the basis of the packaging. For example in the case of 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.

The MEB can permit additions which do not sound Dutch, but which are regarded as extremely commonplace. A condition is that these comply with the following supplementary conditions:

- 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.
- Finally, in all cases, the foreign term in the product name should not result in any confusion.

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.

9.1. The indication

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. The relevant criteria can be found in MEB 21: Statement of 'abbreviated indications' on packaging of OTC products). A request for inclusion of an abbreviated indication on 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 the product name subject to the following conditions:

- The abbreviated indication which can be used is laid down in the MEB 21 policy document: Statement of 'abbreviated indications' on packaging of OTC products).
- The pharmaceutical form is part of the product name (in other words 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 such as Imigran (for migraines) is acceptable in this context.

9.2. Special age groups

If a pharmaceutical product is intended for use by a specific age group, this age group should also be stated on the packaging (see revised Directive 2001/83/EC). However, this information may not be included in the name. The age category must be stated as accurately as possible. The MEB only considers a less accurate statement, for example 'for children' or 'juniors', to be acceptable if the age group is clearly described elsewhere on the packaging. For example: 'for children aged between 1 and 8 years'.

The MEB is of the opinion that referring to the age group is only desirable if, in addition to the product, another product is authorised which is intended for different age group. This policy prevents having to add 'adults' to the packaging of all products that have not been studied, for example, in children. For more information see the MEB 6 policy document: Labelling of pharmaceutical products.

9.3. Use of prefixes and suffixes

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.

9.4. 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. An exception to this is the functional addition of a combination of numbers and letters that have been commonplace for a long time and are therefore indispensable to avoid confusion, such as vitamins (for example Vitamin D3).

9.5. Other additions

Permitted additions:

Addition	Specific details
hyphen (- or dash)	Permitted.

symbol ® or ™	Permitted in the name, when stating the name on the packaging and in the package leaflet. The addition of these symbols is not permitted in the Summary of Product Characteristics. See the document by the European level working party ' <i>Quality Review of Documents</i> ' QRD. Such symbols are therefore not stated on the marketing authorisation.
'Kit' 'Combination package'	Permitted

Permitted under specific conditions:

'sugar-free' 'gluten-free' 'no preservative' 'CFC-free'	These terms are permitted for the purposes of health education. Other similar terms for 'free from' certain substances are not permitted.
'Forte' 'Mitis' 'Extra' 'Extra strong'	Permitted, provided that the strength is included in the name in quantitative terms. Another condition is that several strengths are registered of the same active substance. It is not permitted to use these additions as a claim to emphasise certain characteristics. In other words, it is not permissible to indicate the strength in only qualitative terms.
'cardio'	'cardio' used to be permitted due to the practical application. This addition is only permitted in combination with acetylsalicylic acid.
'retard' 'CR'	Permitted, provided that it characterises the pharmaceutical form.
'IV' 'IM' 'SC'	Permitted, provided that it characterises the route of administration.
'Plus'	Additions to indicate that the product consists of a combination of two or more active substances are permitted provided that both substances are mentioned in the name. 'Plus' is not permitted as a claim to emphasise certain characteristics (see below).
'with citrus flavour', 'menthol', 'mint', 'spearmint', etc.	Permitted provided that it is in accordance with the product's composition and that it relates to a neutral description of the flavour. (Taste) Sensations, such as 'Hot', 'Cool', 'Cool Mint', 'coolmint', 'Fresh', 'Fresh Mint', 'freshmint', etc. are not permitted because these are deemed promotional.
'Easyhaler', 'Clickhaler', 'Turbohaler', 'Autohaler'	Permitted, provided that 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 ' <i>instant</i> ' and ' <i>quick</i> ' can be interpreted in different ways such as fast-acting or for immediate use. This can cause confusion.
'Combi' 'Comp'	Not permitted because this can suggest both a combination product and a combination package. Kit or Combination package are permitted for combination packages.
'Co-' '-Plus'	The additions to the name Co- and -plus (for example, Co-X and X plus) are not permitted for combination products if one of the active substances of the combination product in question is also available on the market 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 9.3).

10. Special products/situations

10.1. Combination packages and combination products

Combination package

Combination packages are packages which contain more than one medicinal product and are marketed under a single trade name and 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 stating the pharmaceutical form in the name of combination packages. If both products have the same pharmaceutical form, it is not necessary to repeat the pharmaceutical form. However, if different pharmaceutical forms are used, all pharmaceutical forms should be stated. In addition, the strengths of the active substances must be separated from each other in the product name by the word 'and' or a plus sign (+).

Only the name of the combination product should be stated on the outer packaging. The name of the combination product is also stated on the individual components, with the substance name contained in the individual component listed below.

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/cholecalciferol 500 mg/880 IU, effervescent granulate

Combination product

A combination product is a product with a combination of active substances 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 previously 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 case of three or more active substances.

A completely invented name must be used for combination products or, if the name refers to the active substances, a reference to all the substances must be included. The sequence of the strength must correspond to the active substances referred to in the product name. In the product name the different strengths of the various active substances which are present in a single combination product are separated from each other by a slash sign (/).

Example: Calci-kit D3 500 mg/800IU/70mg

This name is **not permitted**. As evidenced by the strength, this product consists of 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/800IU

This name is **permitted**. This product refers to all three active substances, namely alendronic acid, calcium and vitamin D3. The sequence of the strength statements must correspond to the sequence of active substances referred to in the product name.

10.2. 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 nomenclature (i.e. pharmaceutical form, strength and/or any additions).

10.3. 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.

Exceptions to the above-mentioned condition:

- 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.

10.4. 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.

10.5. Vaccines

If a new serotype is added to vaccines that consist of various serotypes, the original invented name can be maintained. In that case the name of the vaccine is followed by the number of serotypes present and the pharmaceutical form. The description of the serotypes is shown in the qualitative and quantitative composition, for example:

'Invented name' X serotypes suspension for injection.

The above also applies if 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.

10.6. Biologicals

If changes to the production of a biological (for example, in the case of line extensions) result in a new form of the product and the old product is replaced, a decision will be made on a case-by-case basis whether the existing product name can continue to be used. If the characteristics of a certain product have changed (for example due to the addition of an adjuvant), a name change may be essential.

10.7. Radiofarmaca

Exemption from use of the Dutch language is permitted for the radiopharmaceuticals and for medicinal products for which the MEB (in very exceptional circumstances) has granted an exemption from having to apply a Dutch label. In these cases, the foreign name on the label would differ from the name in Dutch, which could result in confusion and is therefore undesirable.

11. Related documents

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 information about the use of INNs of pharmaceutical substances in the nomenclature of medicinal products.

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 drafted by the CHMP for names of pharmaceutical products processed via the Centralised Procedure.

Via CMD

- 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).

Via MEB

- MEB 5: Package leaflet of pharmaceutical products
- MEB 6: Labelling of pharmaceutical products
Policy documents by the MEB regarding the package leaflet and the labelling of medicinal products. These documents provide an explanation of the information in the Medicines Act.
- MEB 21: Statement of 'abbreviated indications' on packaging of OTC products

Via Wetten.Overheid.nl

- Medicines Act
- Medicines Act Regulation