



# **AESGP Position Paper**

Industry Guidance on Umbrella Names for Non-Prescription Medicinal Products

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### Introduction

This guidance is a technical document focusing on Non-Prescription Medicines (NPM) aimed at guiding companies entering the self-care sector on how to develop umbrella names that resonate with users, but remain distinct enough to avoid product confusion, retaining the priority of user safety. Its secondary objective is also to address authorities' concerns regarding umbrella names.

Umbrella names are used where multiple medicinal products are marketed under a single brand name and can support the self-care environment by helping to avoid numerous individual product references. A unified brand helps with recognition and prevents fragmentation of user attention across too many competing messages or subbrands. A strong umbrella name can convey reliability, safety and efficacy, building trust and consistency, which is especially important in the self-care environment.

Brand names aid users in selecting the right products by signalling the brand's meaning or therapeutic space (e.g., a brand may represent pain relief or allergy symptom control). A brand is also associated with a company's reputation, and as such, the brand can also ensure accountability for the provision of a safe, effective, and high-quality product. Additionally, the brand is not limited to the name of the product, but includes the overall identity and perception associated with it, which can help users navigate a variety of non-prescription therapeutic options to make the best choice to treat their personal needs.

Self-care companies commonly use umbrella names for their NPM. Before submitting an umbrella name for approval of a new NPM, a thorough internal process takes place in designing and reviewing the brand. Several functions are involved in the evaluation to reduce the risk of confusion between the core brand or parent product and the new product due to the name.

This document provides useful recommendations and a general framework. However, it does not supersede local requirements and guidance on umbrella names and packaging. National language and cultural specificities also need to be factored in. Some naming essentials and points to consider during the development of umbrella names are mentioned in Annex I.

Non-prescription medicines (NPMs) have been granted non-prescription legal status after a thorough evaluation of the criteria highlighted in Article 71 of the current pharmaceutical legislation and demonstration that none are met. In particular, and based on pharmacovigilance data, the medicinal product has proven:

- low general toxicity and no relevant reproductive toxicity, genotoxic or carcinogenic properties
- low risk of serious known adverse reactions in the general population
- very low risk of serious unknown reactions
- no interactions with commonly used medicines which can produce serious adverse reactions.

The safety profile of NPMs is well-known. When considering an umbrella name for a new product, the safety profile should be compared to that of the core brand or parent product already on the market.

This is why it is important that assessments regarding a proposed umbrella name and the impacts that such a name may have on user safety and product understanding need the involvement of pharmacovigilance and safety experts, regulatory functions, and medical affairs experts.

# Umbrella branding: general considerations related to user safety

Where an umbrella name is proposed to be used for more than one product, the Marketing Authorisation Holder (MAH) should ensure that the proposed umbrella name does not introduce any risk of confusion from the user or healthcare professional (HCP) about the product use.

MAHs should pay special attention to the following areas when assessing umbrella branding feasibility:

- Different active substances for use in different therapeutic areas
- Different active substances for use in different indications
- Active substances' specific safety profile
- Different target populations and/or different modes of action
- The safety profiles of the products are different in **special populations** (e.g. pregnancy, breastfeeding, hepatic or renal impairment, paediatrics or elderly), or have safety considerations in **different populations** (e.g. different demographic groups)

- The product interactions (e.g., drug-drug, drug-food) are different
- Posology and route of administration are different
- Significant differences in warnings, precautions, and/or contraindications
- If one or more of the products have a more significant risk of user allergy

To reduce the probability of incorrect use and harm, the overall goal is to display concise and easy-to-comprehend instructions and information that would guide proper use. It is also important that not only is the information present, but that the information is displayed clearly and prominently.

Several options may provide mitigation and reduce the probability of incorrect use and harm; some of them are described below. In addition, real-world data (such as post-marketing data) of similar brands may be utilised to guide the MAH to anticipate potential areas where incorrect use may occur. Post-marketing data is also discussed below.

#### **Risk assessment and mitigation**

Brands in general, and umbrella branding names in particular, can be critical to guide users in selecting the appropriate self-care treatment. However, the name of a NPM should, as a matter of principle, not create any public-health concern or potential safety risk. The acceptability of any new proposed invented name should be reviewed to ensure that a name of a NPM is not causing confusion with the name of another product, in a way that such confusion could lead to issues with respect to the safe use of these products.

The name evaluation requires specific risk assessment, especially in case of umbrella branding when developing new products, rebranding existing products or when assessing in-license products as part of an existing brand. The use of risk assessment tools, such as the example in Annex II, can be helpful to drive assessment and enable generation of supporting documentation as needed, and to explore alternative brand names if necessary.

During an umbrella name risk assessment, if potential risks are identified, each one should be assessed to determine whether a risk mitigation measure could eliminate or reduce the likelihood and/or the impact of the risk.

# Examples of potential mitigation measures include (but are not limited to):

• Addition of a qualifier or suffix/prefix to differentiate the product. For example, highlighting target population groups, indication, therapeutic area, etc., if this would differentiate and improve selection and safe use.

- Important information should be prominently displayed, with tools used (e.g., colour, boldness, prominent placement on pack or primary packaging) to appropriately convey this. Boldness or noticeability should be commensurate with the level of safety risk to ensure the user's attention is directed towards very important information that may impact safety. Additionally, icons, symbols, or other visual imagery should be used to draw the user's attention to key differences and/or safety information.
- **Simplification** of language to describe concisely the key information: applying plain language principles by using features that increase readability and reading comprehension for critical information to maximise differentiation, such as creating ample white space, using language commonly understood by users, modifying font, format, and/or graphics for key information.
- (both primary and secondary packaging) to ensure user awareness of risk or to bring awareness to product differences. For example, products with distinctly different package types, colours, fonts, material transparency (e.g. translucent vs opaque) may be very clearly different from each other in the mind of the user, helping the user to understand that there is an inherent difference.

 Studies to demonstrate that users can differentiate the products, if deemed appropriate by the marketing authorisation holder (MAH).

Once the proposed mitigation measures are identified, they should be evaluated to establish if this reduces the potential risk sufficiently, or whether any additional measure should be put in place or an alternative brand name is necessary.

The use of risk assessment tools is recommended to be used as early as possible in the development process of the product name. However, the use of an assessment tool is a recommendation and not an obligation, each MAH should choose the strategy they consider most appropriate to assess naming of its NPM.

#### Pharmacovigilance and post-marketing monitoring

To effectively identify safety issues associated with products marketed across umbrella names, companies can use pharmacovigilance data to gain insights into real-world product usage to proactively identify potential gaps associated with safe use.

Approaches that could be used include pharmacovigilance tools such as quantitative and qualitative analysis, and aggregate report analysis to identify areas where safety mitigations could increase safe product selection and use. An example of how to use pharmacovigilance data, to monitor for product confusion or misuse is further discussed in Annex III, where the utilisation of MedDRA System Organ Class (SOC) and High-Level Term (HLTs) is illustrated as a method to examine data related to product confusion. These terms specifically highlight many of the potential consequences that can occur if an umbrella-branded product is not properly

mitigated with clear product information that sufficiently guides the user through the product selection and understanding process. Therefore, it is critical that a MAH not only attempts to anticipate these challenges during the product development phase but also continues to monitor the data in the postmarketing phase to understand any real-world use and other unanticipated challenges that may arise.

Additionally, similar data may be collected outside of pharmacovigilance in companies that deal with users' queries or complaints. Consideration should be given to monitoring any changes in trends related to safety observations or users' complaints when introducing a new umbrella name. Further risk mitigation activities should be considered if any post-marketing risk has been identified or confirmed.

# Umbrella branding: possible cases and associated guidance (Annex IV)

There might be different situations in which a marketing authorisation holder (MAH) would like to use umbrella branding names. Depending on the scenario and umbrella branding architecture, measures should be applied to allow proper identification of the medicinal product.

#### Scenario A

The proposed product contains the **same active substance(s)** and has the **same indication** as the existing one, but differs, e.g., in strength, pharmaceutical form, route of administration, or target population.

Special areas of focus should include (but are not limited to):

- Clear presentation and differentiation of product strength, pharmaceutical form, and/or route of administration (e.g., consider use of a qualifier and/or indicating the above on the front of the pack, using appropriate fonts, colours, icons, etc.)
- Highlighting product target population (e.g., if a new product is indicated for children, use an appropriate qualifier as a part of the umbrella name, such as "Junior", "Children", "Infants", etc.)

#### Scenario B

The proposed product contains the **same active substance(s)**, is used in the **same or related therapeutic area** to the existing one, but differs, e.g., in indication, strength, pharmaceutical form, route of administration, or target population.

Special areas of focus should include (but are not limited to):

- Clear presentation and differentiation of product indication (e.g., consider using descriptive and informative qualifiers about indication or therapeutic area, such as "Cardio", "Flu", "Sinus", etc.)
- Clear presentation and differentiation of product strength, pharmaceutical form, and/or route
  of administration (e.g., consider indicating the above on the front of the pack, using
  appropriate fonts, colours, icons, etc.)
- Highlighting product target population (e.g., if a new product is indicated for children, use an appropriate qualifier as a part of the umbrella name, such as "Junior", "Children", "Infants", etc.)

#### Scenario C

The proposed product contains **additional active substance(s)** and the **same indications** as the existing one, but differs, e.g., in strength, pharmaceutical form, route of administration, target population, and additional properties achieved by the added active substance.

Special areas of focus should include (but are not limited to):

- Clear indication of product composition and strength, focusing on composition differences (e.g., consider using an informative qualifier, prefix, or suffix in product name, visible on the front pack)
- Clear presentation and differentiation of pharmaceutical form, route of administration, and/or target population, if applicable (e.g., consider using appropriate fonts, colours, icons, etc.)

#### Scenario D

The proposed product contains **additional active ingredient(s)** but is for use in the **same therapeutic area** as the existing one, but differs, e.g., in indication, strength, pharmaceutical form, route of administration, or target population.

Special areas of focus should include (but are not limited to):

- Clear indication of product composition, strength, and indication focusing on composition differences and indication (e.g., active ingredient and indication should be displayed prominently, and consider using an informative qualifier, prefix, or suffix in the product name, visible on the front pack.)
- Clear presentation and differentiation of pharmaceutical form, route of administration, and/or target population, if applicable (e.g., consider using appropriate fonts, colours, icons, etc.)

**Note**: The name of the product must be given prominence as part of the pack labelling, with a special focus on the qualifier or prefix/suffix. The suffix or prefix should not give rise to inappropriate impressions of superiority or ambiguity. A basic pack design (format, fonts, colours, icons, etc.) that highlights key differences could differentiate between products.

#### Scenario E

The proposed product contains additional active ingredient(s) and is for use in a related therapeutic area to the existing one, but differs, e.g., in indication.

Special areas of focus should include (but are not limited to):

- Clear indication of product composition, strength, indication, and therapeutic area, focusing
  on composition differences and indication (e.g., active ingredient and indication should be
  displayed prominently, and consider using an informative qualifier, prefix, or suffix in product
  name, visible on the front pack.)
- Clear presentation and differentiation of pharmaceutical form, route of administration, and/or target population, if applicable (e.g., consider using appropriate fonts, colours, icons, etc.)
- Clear indication of therapeutic area, especially if the active substance in the existing product name is generally associated with a particular therapeutic area, the name of the product should differ from existing product(s) with special focus on therapeutic area (e.g., consider using descriptive and informative qualifier about therapeutic area, such as "Cardio", "Flu", "Sinus", etc.)

**Note**: The name of the product must be given prominence as part of the pack labelling, with a special focus on the qualifier or prefix/suffix. The suffix or prefix should not give rise to inappropriate impressions of superiority or ambiguity. A basic pack design (format, fonts, colours, icons, etc.) that highlights key differences could differentiate between products.

#### Scenario F

The proposed product contains **different active ingredient(s)**, but has the **same indication** as the existing one.

Special areas of focus should include (but are not limited to):

• Clear indication of product composition focusing on active substance differences (e.g., consider using informative qualifier, prefix or suffix, displayed prominently on the front pack, and appropriate pack design, such as fonts, colours, icons, etc. to highlight key differences).

#### Scenario G and H

The proposed product contains different active ingredient(s), but it is for use in the same or a related therapeutic area to the existing one.

Special areas of focus should include (but are not limited to):

- Clear indication of product composition, indication, and therapeutic area (especially if related therapeutic area), focusing on active substances differences and indication (e.g., active ingredient and indication should be displayed prominently, and consider using an informative qualifier, prefix, or suffix in product name, visible on the front pack.)
- Clear presentation and differentiation of pharmaceutical form, route of administration, and/or target population, if applicable (e.g., consider using appropriate fonts, colours, icons, etc.)
- Clear indication of the related therapeutic area, especially if the active substance in the
  existing product name is generally associated with a particular therapeutic area, the name of
  the product should differ from existing product(s) with a special focus on therapeutic area
  (e.g., consider use of descriptive and informative qualifier about therapeutic area, such as
  "Cardio", "Flu", "Sinus", etc.)

**Note**: The name of the product must be given prominence as part of the pack labelling, with a special focus on the qualifier or prefix/suffix. The suffix or prefix should not give rise to inappropriate impressions of superiority or ambiguity. A basic pack design (format, fonts, colours, icons, etc.) that highlights key differences could differentiate between products to emphasise the difference to users and help them select the appropriate product.

Cases where the proposed product contains differences in composition compared to the existing one, has different indications, and is being used in an unrelated therapeutic area should be assessed carefully in the context of potential safety concerns. If the safety assessment is positive (i.e., a safety or risk has been identified), an appropriate name modification and product pack presentation should be applied (using some of the above-listed scenarios).

# **Annexes**

## Annex I - Naming essentials

Points to consider	Details
Use of qualifiers (e.g., Children's)	<ul> <li>Consider that the inconsistent use of qualifiers and the absence of a standardised meaning for such terms can be confusing to end users. Concerns sometimes arise with descriptive qualifiers that are ambiguous, misleading, or subject to misinterpretation.</li> <li>Consider whether the qualifier's intended meaning is supported by the proposed labelling and whether it is understood by the end user. Example: the labelling of a product as "Children's" may be considered misleading if the product is also intended to be used by infants and/or adults.</li> </ul>
Cross-market branding reflections	<ul> <li>Consider in-market experience where the product is marketed and whether any product in the launch country might be identical, or virtually identical in spelling and pronunciation.</li> </ul>
Rx to OTC switch	<ul> <li>Consider the basis for the continued use of the original proprietary name when full switch vs. partial switch, and the extent to which differentiation is appropriate.</li> </ul>
Use of symbols/numbers/ abbreviations	Consider that symbols can be misinterpreted or confusing (e.g., "+" can be read as "4", 100 may be perceived as 100%). Qualifiers/ abbreviations within the invented name should aid selection/identification/differentiation of the product by the user and should minimise the risk of inappropriate use.
Use of the MAH name in the proprietary name	<ul> <li>Consider that practice can result in creating multiple similar proprietary names for dissimilar products, which might increase the risk of confusion.</li> </ul>
Country-specific naming	<ul> <li>Consider country-specific issues/ guidance /restrictions, etc.</li> <li>Consider the pronunciation of the name in the intended countries. The name should not be offensive or have an inappropriate connotation in the language of the intended countries.</li> </ul>
Are there medical abbreviations and / or coined abbreviations (have no meaning) in the proposed name?	<ul> <li>Consider that medical abbreviations (e.g., QD, BID) or others commonly used for prescription medicines could inadvertently be a source of error.</li> </ul>

Points to consider	Details
Use of product attributes/claims in the name?	<ul> <li>Consider that words or phrases in brand names should not overstate product efficacy, minimise risk, broaden product indications, or make unsubstantiated superiority claims. A name should not convey a promotional message.</li> </ul>
Reuse of discontinued proprietary names?	<ul> <li>Consider the potential risk that users may continue to associate the name with the original discontinued product.</li> </ul>
Inert or inactive ingredients referenced in the proposed name?	<ul> <li>Consider whether inert/inactive references in name create an impression that the ingredient's value is greater than its true functional role in the formulation.</li> </ul>
Reference to single active ingredient only in brand name for combinations containing multiple actives (e.g., for line extensions)?	<ul> <li>Consider if proprietary names of fixed combination drug products include or suggest the name of one or more, but not all, of their active ingredients, and if so, implications for the end user's awareness that the product contains only the ingredient(s) included in the name.</li> </ul>
Inclusion of dosage form, route of administration, manufacturing characteristics, symbols, or dosing interval in the name?	References to product-specific attributes in the root proprietary name should be consistent with the product's labelling and not pose additional risks for medication error. Consider that future changes in dosage form, route of administration or manufacturing characteristics may render the original proprietary name inaccurate.
Confusion between the invented name/common name.	<ul> <li>An invented name shall not be liable for confusion with the common name (active substance/INN).</li> </ul>

#### Annex II - Risk assessment table

#### NON PRESCRIPTION MEDICINES

		Cor	e brand pro	oducts	Ne	ew candida	ate													
Product name																				
Steps																				
1 D		H	ligh	Medium Lo			ow													
1. Degree of	a. Print (product name)																			
orthographic, phonetic and	b. Speech (product name)	)																		
graphic similarity	c. Graphics																			
grapme similarity	d. Cognitive error																			
	Points to consider:						Core branc	d products	New ca	w candidate Consequence of difference			ice	Is there an		risk	Yes	No	N/A	
	Active ingredient(s)														identified?					
	Indication														Strategies	to help red	uce potenti	al risk iden	tified	
	Therapeutic class																			
	Mode of action																			
	Target population																			
	Contraindications																			
2. Setting of use	Warnings & Precautions																			
2. Setting of use	Possible risk identified at SELECTION level?					Ye	es	N	lo .	N/	Ά	Unc	lear							
	Possible fish identified at SELECTION level?																			
	Points to consider:						Core branc	d products	New ca	ndidate	Consequence of difference			ice	Is there an		risk	Yes	No	N/A
	Route of administration														identified?					
	Max. daily dose and duration													Strategies to help reduce potential risk identified						
	Possible risk identified at ADMINISTRATION/HOW TO USE level?					Ye	es	N	lo	N/	Α	Unc	lear							
Preliminary discussi	on and next steps																			
Final conclusion / re	ecommendation																			

#### How to perform the assessment:

- 1. Compare the existing Core Brand/Parent Product to the New Candidate in terms of similarity of print, speech and graphics. In case of medium or high similarity, is this similarity likely to lead to a cognitive error?
- 2. Compare the existing Core Brand/Parent Product to the New Candidate in terms of key safety profile elements and describe the consequence of difference between the existing brand and the new candidate in the event of product confusion.
- 3. Confirm if a potential risk was identified and propose strategies to help reduce potential risk.
- 4. Identify/evaluate proposed mitigation measures, discuss next steps and evaluate the effectiveness of mitigation measures.
- 5. Propose name and recommendations.

#### **Additional information:**

To facilitate the assessment of the consequences of differences in Point 2, some questions may be considered to help assess the likelihood and impact of the difference, namely:

Topic	Questions
Active Ingredient(s)	<ul> <li>Does this product share at least one common active ingredient with other products in the same brand?</li> <li>Is the umbrella name associated with an active ingredient that is not in this new product?</li> </ul>
Indication	<ul> <li>Does this product have a similar indication to the other products in the brand?</li> <li>Is the umbrella name associated with an indication that this product is not indicated to treat?</li> <li>Do you consider that users will understand that the product has a different indication than usually associated with this umbrella name?</li> <li>Do you consider that users will be able to differentiate between the products and choose the correct one for their symptoms?</li> <li>If indications are different:</li> <li>Do you consider it likely that a user could take the product for the wrong indication?</li> <li>If taken for the wrong indication, what is the risk from unnecessary exposure to an active ingredient?</li> <li>If taken for the wrong indication, is there a risk of aggravation of the preexisting condition if untreated?</li> </ul>
Therapeutic Class Mode of Action	<ul> <li>Does this product have the same or similar mode of action as other products with the brand name?</li> <li>Does the product have the same impact on the body at the cellular level?</li> <li>Does the product belong to the same therapeutic class?</li> </ul>
Target population	<ul> <li>Does this product have a different target population (e.g. paediatric vs. adult, overlap between contraindication/warning and precaution, or target population(s))?</li> <li>Does this product have a contraindication/warning and precaution that overlaps with the target population of other products in the same brand?</li> <li>Do you consider that the user understands if the product is intended for a different audience?</li> </ul>

#### Warnings & Is there a risk of a user taking this product together with another **Precautions** product from the same brand that could result in overdose of an ingredient or drug-drug interactions? If users take more than one product from the umbrella name, could there be serious consequences? Does the user understand if the new product has the same ingredient and shouldn't be taken simultaneously? Route of Does this product have a different route of administration that could administration lead to clinically significant adverse events or sequelae? If the user uses the product incorrectly, could it lead to a serious side effect or event? (e.g., putting a nasal spray in the eye) Do you consider that the user recognises the need to use it differently? (i.e., oral, topical, ophthalmic, nasal, rectal, sublingual) Max. daily dose Is the recommended posology (about strength, dose and dosing interval) different than other products in the same brand? and duration If a user takes the wrong strength or dose of the product, could it result in serious adverse events? If a user does not follow the recommended dosing interval, could there be serious adverse events? Do you consider that the user understands if the product is a different strength than other products in the umbrella name? Is there a risk of a user taking this product together with another product from the same brand that could result in serious consequences? Do you consider that the user understands if the new product has the same ingredient and shouldn't be taken simultaneously?

#### **Annex III - Continued learning: Post-marketing data**

Points to consider for understanding user behaviour with umbrella branding in the post-marketing setting:

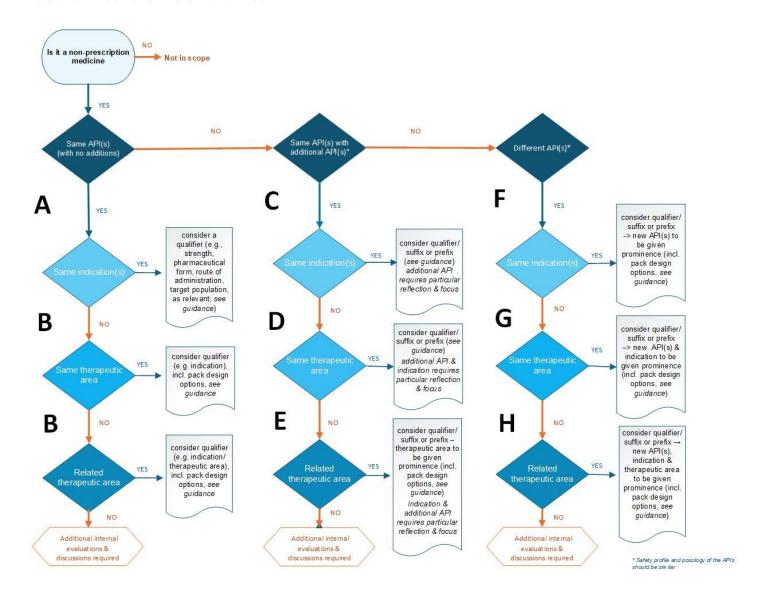
- Once a product(s) is commercialised under an umbrella name, it is important to continue to monitor the available real-world data (e.g., post-marketing safety data, product complaint data) for patterns or trends that may indicate accidental incorrect use, misuse, or other indicators that umbrella branding may be impacting the user selection/use in a non-optimal way regarding safety and effectiveness.
- MAHs can utilise certain MedDRA terms to investigate indicators of misuse in the post-marketing data. When using MedDRA, the System Organ Class (SOC) "Injury, poisoning and procedural complications" can be filtered down to the High-Level Term (HLT) "Product Confusion Errors and Issues". This grouping contains a range of Preferred Terms (PTs) that can provide valuable insights into whether there have been reports of product selection and use experiences that could indicate suboptimal outcomes associated with the umbrella name. Please see the list of PTs in the image below from MedDRA<sup>1</sup>.

 SOC: Injury, poisoning and procedural complications HLGT: Medication errors and other product use errors and issues + HLT: Accidental exposures to product + HLT: Medication errors, product use errors and issues NEC + HLT: Product administration errors and issues HLT: Product confusion errors and issues + PT: Device use confusion + PT: Product appearance confusion + PT: Product confusion + PT: Product design confusion + PT: Product dosage form confusion + PT: Product dose confusion + PT: Product label confusion + PT: Product name confusion + PT: Product packaging confusion + PT: Product regimen confusion + PT: Product strength confusion **PT**: Use of error-prone abbreviation

<sup>&</sup>lt;sup>1</sup> https://www.meddra.org/how-to-use/basics/hierarchy

As the post-marketing data, product complaint data, and any other real-world data are monitored, these activities can provide insights into trends and identify potential gaps or areas of misuse that may be mitigated to enhance user understanding and promote safe and effective product use. It can also be used as supportive evidence to help reassure that the umbrella name does not create any confusion or additional safety concerns. Additionally, it can provide valuable insights when a company is evaluating umbrella segments for products in development, highlighting potential areas of confusion and ways to improve aspects such as product labelling and packaging features. This can include simplification of language, optimising placement, typography, and colours and symbols to effectively convey critical information that guides safe use.

#### Annex IV - Decision tree for umbrella names



# **Glossary of terms**

Term	Definition
Cognitive error	In some cases, even though two invented names do not share the same letters in the same order, there is a risk of potential confusion in relation to the way the human brain perceives them; this is considered a cognitive error associated with at least a medium degree of similarity in print, speech, and handwriting.
Core brand/parent product	A parent product is an existing product that gives rise to a brand name extension.
MedDRA	Standardised medical terminology developed by ICH to facilitate the sharing of regulatory information internationally for medical products used by humans. It is used for registration, documentation, and safety monitoring of medical products both before and after a product has been authorised for sale. Products covered by the scope of MedDRA include pharmaceuticals, vaccines, and drug-device combination products.
Prefix	A letter or group of letters added to the beginning of a word to make a new word.
Qualifier	A word (or words) that limits or modifies the meaning of another word or collection of words.
Suffix	A letter or group of letters added to the end of a word to make a new word.
Umbrella names	Extension of the invented brand name across different medicinal products.

# **Abbreviations**

**HCP** – Healthcare professional

**HLT** – High-level term

**INN** – International non-proprietary name

**MAH** – Marketing authorisation holder

**NPM** – Non-prescription medicinal products

PT - Preferred terms

**SOC** – System organ class

### References

- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.
- EMA Guideline on the acceptability of names for human medicinal products
   processed through the centralised procedure (EMA/CHMP/287710/2014 Rev.
   7)https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure-revision-7\_en.pdf
- Good pharmacovigilance practices
   https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/good-pharmacovigilance-practices-gvp
- Good practice guide on risk minimisation and prevention of medication errors (EMA/606103/2014)
   https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/good-practice-guide-risk-minimisation-and-prevention-medication-errors\_en.pdf
- Guideline on the readability of the labelling and package leaflet of medicinal products for human use (Revision 1, 12 January 2009) <a href="https://health.ec.europa.eu/document/download/d8612682-ad17-40e3-8130-23395ec80380">https://health.ec.europa.eu/document/download/d8612682-ad17-40e3-8130-23395ec80380</a> en
- WHO publication on medication safety for look-alike, sound-alike medicines <a href="https://www.who.int/publications/i/item/9789240058897">https://www.who.int/publications/i/item/9789240058897</a>

