

# **MHRA GUIDELINE FOR THE NAMING OF MEDICINAL PRODUCTS AND BRAILLE REQUIREMENTS FOR NAME ON LABEL**

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## Introduction

1. The purpose of this guideline is to provide industry with clear guidance on the factors which need to be considered when selecting or constructing a product name. Notwithstanding the guidance provided, applicants should take into account the principles contained within the Best Practice Guidance on the Labelling and Packaging of Medicines<sup>1</sup>, including prominent display of the active ingredient(s) and pack design/graphics clearly differentiating products and should conform to the requirements of Directive 2001/83/EC. The MHRA does not comment on issues arising from protection or infringement of trademarks. This guideline does not contain any new legislation or requirements but consolidates all current requirements into a single document, giving specific examples where appropriate, to aid applicants when selecting a product name.
2. The name of the medicinal product means the name, which may be an invented name not liable for confusion with the common name, or a common or scientific name. This name will be stated in section 1 of the Summary of Product Characteristics and consequently displayed on the label. It should be followed by its strength and pharmaceutical form in accordance with Articles 1(20), 11(1), 54(a) and 59(1)(a) of Directive 2001/83/EC. In all cases the three components of “name of medicinal product”, “strength” and “pharmaceutical form” are regarded as separate entities.
3. The Licensing Authority may reject a name if it considers that, on the information given, or in its own assessment, the name will cause confusion with the name of an existing medicine, is misleading as to the composition of the product or the use, or is otherwise unsafe. Sections 5 to 17 provide more detail about specific reasons to reject names.
4. Approval of a name by the Licensing Authority does not relieve the MA holder of responsibility should actual or potential hazards come to light following marketing of the product. In these circumstances the Licensing Authority must be advised and appropriate action taken.

# Criteria Used in Assessing the Suitability of Invented Names for use in Medicines

## General Principles

### 5. Legislative Requirements

Directive 2001/83/EC requires that an invented name should not be liable to confusion with the common name or the name of any other medicinal product. In addition invented names should not be misleading with respect to the following:

- therapeutic effects of the product;
- composition of the product;
- safety of the product;

### 6. Promotional or Misleading Claims

- The invented name of a medicinal product should not convey misleading therapeutic and/or pharmaceutical connotations;
- the invented name of a medicinal product should not convey promotional connotations, e.g. the indication of the strength of a product in an invented name by words such as “forte” or “strong” should be avoided.

### 7. Safety Concerns and Confusion with Another Medicinal Product

MHRA assesses each invented name individually and in conjunction with a specific medicinal product. Where the proposed invented name has been registered as a trademark in the UK for use with a medicinal product, an assessment by MHRA, including safety considerations, determines whether the proposed invented name is suitable for use for the medicinal product. MHRA assesses each invented name to minimise the potential risk of confusion with the name of another medicinal product.

When reviewing the acceptability of proposed invented names, MHRA applies criteria based on public health concerns. Obtaining a trademark for the proposed invented name is not considered justification alone for accepting a proposed invented name.

The Applicant/MAH would be expected to review the proposed invented name, applying the criteria outlined in this guideline, before requesting that an invented name be considered.

The invented name should not comprise wholly of initial letters or code numbers.

The invented name of a medicinal product should not be liable to cause confusion in print, handwriting or speech with the invented name of another medicinal product. When assessing the potential for such confusion, the following aspects are considered systematically:

- The indication(s);
- Patient population(s);
- The pharmaceutical form(s);
- The route(s) of administration;
- The strength(s);
- The setting for dispensing and use;
- The legal status/ classification for supply (i.e. medicinal product subject to medical prescription, medicinal product not subject to medical prescription, medicinal product subject to restricted and/or special medical prescription).

#### **8. Similarity with International Non-proprietary Names (INN) and/or British Approved Names (BAN)**

Where a similarity between a proposed invented name and an existing INN and/or BAN is identified, the following criteria should be taken into consideration:

- The closeness either in speech, print or handwriting with its own or a different INN; in accordance with World Health Assembly Resolution (WHA) 46.19 an invented name should not be derived from its own INN;
- The similarity in medicinal setting, general use (indication) of concerned medicinal products;
- The similarity in classification for supply of the concerned medicinal products e.g. restricted to hospital setting, specialists;
- The route(s) of administration and, where possible the concerned pharmaceutical forms.

The Applicant/MAH would be expected to review INN and/or BAN similarity before requesting that the proposed invented name(s) be considered.

## 9. Published INN stems

Invented names should not contain INN stems in the stem location as published by WHO. This is in accordance with WHA Resolution 46.19 that indicates “It would therefore be appreciated if invented names were not derived from international non-proprietary names (INNs) and if INN stems were not used in invented names”.

A full list of INN stems is available on the WHO website (reference WHO/PSM/QSM/2006.3).

By including the same INN stem in the invented name as the INN, healthcare professionals could consider that this is a new active substance as opposed to an invented name; by including a different INN stem healthcare professionals could consider that this is a different type of medicine rather than an invented name.

The use of a two letter INN stem in an infix or suffix position in an invented name will be addressed on a case by case basis.

The Applicant/MAH would be expected to review the proposed invented name to ensure an INN stem is not included in the name to be considered.

## Assessing the Suitability of Invented Names for Non-prescription Medicines

Invented names as applicable to all medicinal products should be followed by both the strength and pharmaceutical form. The omission of the strength may be acceptable where it is impractical to include this in the product name, e.g. where there are multiple active ingredients usually containing substances such as glycerol or liquid paraffin. The pharmaceutical form should be described by a single Standard Term of the European Pharmacopoeia<sup>4</sup>.

### General Principles

The following terms which form part of the invented name will only be considered where the specified conditions are met by the applicant. Derivatives of the listed terms with regards to spelling and other connotations, if misleading, will not be approved:

- **Fast acting, Express (including derivatives such as Xpress)** and any other terms indicating a ‘quick’ or ‘fast’ onset of action should only be used where this claim is supported by data in the SmPC and is relevant to the indication(s) for which the product is being marketed for, e.g. onset of action in < 30 minutes from oral administration;
- **One-a-day** should only be used where a unit dose is taken or administered once in a day. Half-a-tablet twice a day, with the justification that the total dose per day is equivalent to one tablet is not acceptable. **Once-a day** may be used where one or more tablets are taken or administered once a day;
- **PLUS, Extra (including derivatives such as Xtra)** should only be used where the medicinal product contains an additional active ingredient which confers a synergistic or additional therapeutic action or benefit;
- **Triple action** should only be used where the medicinal product clearly has three different therapeutic actions. This may be a product with a single active substance with three different actions or three actives with different modes of action. Where the claim has a qualified therapeutic action e.g. ‘Triple action pain relief’, the three different actions must be relevant to pain relief;
- **Advance** should only be used when it can be demonstrated that enhancement has been achieved with the new product compared with the existing product. This may be an enhancement in a therapeutic action or enhancement resulting from a formulation change. The addition of increased amounts of the active and/or excipient(s) without evidence of enhanced therapeutic benefit is not acceptable justification; similarly, minor changes in formulation that do not provide recognisable benefits over the existing product do not constitute enhancement;
- **Maximum strength** should only be used where there are different strengths of products containing the same ingredient and the strength is the maximum available;
- **Original** will only be accepted where there is more than one presentation on the market and this is used to differentiate the initial licensed medicinal product from the others;
- **Flavours** have to be identified as such, e.g. the term ‘strawberry’ in a name is acceptable if there is fruit or natural extract contained in the product, if present as an artificial flavouring will have to be listed as ‘strawberry flavour’ in the product name.



## 10. Informative Invented Names

Special consideration should be given to non-prescription medicines to allow informative names, the basis of which is as follows:

- The invented names of these medicines can aid the patient to select an appropriate product without input from healthcare professionals. It is therefore acceptable for the name of these products to be informative for the patient e.g. Bloggs Pain Relief Tablets;
- These products must comply with section 6; consequently Bloggs Head Pain Away Tablets would not be acceptable as it would be considered a misleading medical claim.

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## **Criteria Used in Assessing the Suitability of Qualifiers/Abbreviations**

### **11. Composition of the Qualifier**

The use of qualifiers/abbreviations by letters as part of the invented name is, in principle, acceptable. Proposed qualifiers should not consist of a single letter or number (Arabic and Roman), because they may be confused with the strength and/or posology of the medicinal product. Numbers in general should only be used to indicate the strength of the medicinal product. In certain cases a number(s) may form part of a qualifier, however, this would be assessed on an individual basis. The applicant should provide justification to MHRA when requesting a qualifier.

### **12. Selection of a Qualifier or Abbreviation**

The following should be taken into account when proposing a qualifier/abbreviation:

- Whether the qualifier/abbreviation provides further information on characteristics of the medicinal product (e.g. duration of action, devices, route of administration, composition, patient population) or provides for a differentiation, which may help healthcare professionals and/or patients to prescribe/select the appropriate medicinal product;
- The potential risk to public health in case of a medication error potentially related to the qualifier/abbreviation versus the potential risk resulting from a more complex name.

### **13. Prolonged-release Preparations**

Applicants are advised that the following suffixes should be used for prolonged release preparations, as appropriate to the particular product:

CR - Controlled release

LA - Long acting

PR - Prolonged release

SA - Sustained action

SR - Sustained release

XL - Prolonged release, once daily dosing. If a product can be given once or twice daily, a different suffix should be used.

MR - The use of MR for a prolonged release preparation is no longer recommended. Modified release can indicate a gastro-resistant product or a prolonged release product, therefore the term is not specific for an individual product.

### **14. Gastro-resistant Preparations**

Applicants are advised that the following suffixes should be used for gastro resistant preparations, as appropriate to the particular product:

EC - Enteric coated

GR - Gastro resistant

## Criteria Used in Assessing the Acceptability of Umbrella Segments of Product Names

### General Principles

An umbrella segment of an invented name is a section of invented name that is used in more than one medicinal name to create a brand or range of products.

Where an umbrella segment is proposed to be used for more than one product, the umbrella segment should not be used if its use is likely to result in safety or efficacy concerns resulting from confusion between the products sharing the same umbrella segment. Such concerns may arise, for example:

- if the products contain different active ingredients;
- if the products can be used in different populations;
- if their safety profile is different in different populations (e.g. one can be used in pregnancy or in patients with renal impairment or in elderly people, and the other cannot);
- if their interactions are different;
- if their features of and treatment for overdose are different;
- if their speeds of onset are different.

### 15. Acceptability of Umbrella Segments

MHRA encourages applicants to develop new product names without umbrella segments for each product; however, the MHRA will consider on its merits each application for a product name including an umbrella segment. MHRA's principal considerations are to ensure that medicines are taken safely and correctly, that a proposed name will not give rise to safety or efficacy concerns and that the name complies with legislative requirements. MHRA does not intend to impose unnecessary impediments to companies using a particular name and recognises that other features, such as pack design, labelling etc. can help distinguish between products.

### 16. Specific Circumstances

- *The proposed product for which an umbrella segment will be used in the name contains additional active ingredients and is for use in the same therapeutic areas as the existing product using the same umbrella segment.*

The proposed product name should be different from the name of the existing product usually by the use of a suitable suffix or prefix. The suffix or prefix should not give rise to inappropriate impressions of superiority or ambiguity.

- *The proposed product for which an umbrella segment will be used in the name contains the same or additional active ingredients and is for use in a different therapeutic area from the existing product using the same umbrella segment in the name.*

If in the opinion of the Licensing Authority the existing product name is associated with a particular therapeutic area, the Licensing Authority will wish to be reassured that extension to a different therapeutic area will not give rise to safety issues. Where the new product contains the same active as the original product, packs may be acceptable where the name is differentiated by a suitable descriptor indicative of the new therapeutic area (e.g. Bloggofen Cold and Flu Capsules and Bloggofen Headache Capsules).

- *The proposed product for which an umbrella segment will be used in the name contains different active ingredients and is for use in the same or different therapeutic area as the existing product.*

If in the opinion of the Licensing Authority the existing original product name is associated with a particular active ingredient, the Licensing Authority will need to be convinced that the use of the umbrella segment will not give rise to safety issues or efficacy issues due to differential efficacy and speed of onset of effect. This scenario is likely to be the most difficult one for which to obtain approval, and applicants are encouraged to develop new product names without umbrella segments for each product. If such association exists, the name should be clearly different from the existing product.

## **17. Factors to be Addressed in Applications**

In order to allow a risk-based assessment of proposed product names including umbrella segments, the MHRA, in its assessment of an application, will consider the factors listed below, as appropriate, in determining whether it considers a product name that includes an umbrella segment is acceptable. The MHRA will also take into account the legal status of the product (i.e. whether ‘POM’, ‘P’, or ‘GSL’).

In order to facilitate MHRA’s consideration of the application, applicants should consider and address the type of factors listed below in their application. A risk analysis for the new application, taking into account all of these points, and considering the impact on existing products sharing the same umbrella segment within their name would facilitate MHRA consideration. Applicants should address how they propose to deal with any potential risks identified or explain why, in their opinion, the identified risks would not present a problem:

- Rationale for the proposal;
- Description of other products within the company’s own range or from another company with the same or similar (either in spelling or phonetic terms) umbrella segment;
- Indications for each relevant product;
- Discussion of any safety issues that may arise from use of the umbrella segment for the new product, should it be confused with other products with the same or similar umbrella segments, based on consideration of the safety profile of the active ingredients;

- Any association between safety and relevant brand(s);
- Specific populations of patients/consumers where differences exist between products with the same umbrella segment e.g. children, pregnant women, elderly people, those with renal or hepatic impairment;
- Differences in interaction with other medicines;
- Differences in indications, contraindications, warnings, posology (including dosing frequency, different strength) and other SPC/PIL information;
- Differences in effects of and management of overdose;
- Differences in the mode and speed of action between active ingredients in products sharing the same umbrella segment of their product name (e.g. heartburn and indigestion containing alginate and antacid or H<sub>2</sub> antagonist respectively);
- Use of different suffixes/prefixes etc and how these may differentiate between products, addressing issues such as strength, population, therapeutic area etc.;
- Details of the pack including:
  - Pack overall colour and design;
  - Pack design shape;
  - Placement and prominence of active ingredient and usage information;
  - Form(s) of product;
  - Inner pack colour, design and shape;
  - Pack size;
  - Ability to differentiate between products sharing the same umbrella segment in their product name.

## **Criteria for the Generic Naming of Medicines, INN or Common name**

### **18. Use of INN or BAN**

Where the applicant wishes to use the generic name instead of an invented name, the following rules should be taken into account:

- If an INN recommended by the World Health Organisation exists for the active moiety the English version of the name should be used exactly as published without omissions or abbreviations. If one does not exist the usual common name should be used, in the UK this is the BAN;
- If a Modified INN (INNM) recommended by the World Health Organisation has been published for the active moiety, it should be used within the name of the medicinal product exactly as published without omissions or abbreviations;
- Where the active moiety is an unpublished INNM the name of the medicinal product should be that as agreed by users of INNs (Pharmacopoeias, regulatory bodies, stakeholders), in accordance with the WHO INNM working document 05.167/3.

### **19. Generic Naming Convention**

Where the applicant wishes to use the generic name, the name should comply with the following format:

- The common name or scientific name should appear together with a trademark or the name of the Marketing Authorisation Holder (MAH). In the UK the usual practice for this is to name the product as the INN followed by the strength and the pharmaceutical form; this appears “together” with the name of the MAH by means of the information on the rest of the packaging;
- Paracetamol Tablets manufactured by Bloggo Laboratories Limited would usually be named as “Paracetamol 500 mg Tablets”, the term “Bloggo Laboratories Limited” would be visible on the labelling of the packaging. In this instance the name of the company is reasonably long and the company may wish to use the company trademark (trading style) for example BLtd. This would be acceptable as long as the term BLtd is used as the company trademark.

Where the applicant wishes to incorporate the company name in the generic name, the name should comply with the following format:

- Although discouraged by MHRA because of potential confusion, an applicant is permitted to incorporate the company name or trademark into the name of the medicinal product directly after the INN/common name. The acceptable trademark is the trading style of the manufacturer. Using the above example, an acceptable generic name would be:
  - “Paracetamol Bloggo Laboratories Limited 500 mg Tablets”;
  - “Paracetamol BLtd 500 mg Tablets”;
- Where the applicant wishes to incorporate the company name or trademark into the generic name, the company name or trademark must be positioned directly after the INN/common name;
- Inclusion of a company name within the name of the medicine will not be permitted when there is not sufficient space on the packaging;
- Applicants should note the implication for Braille requirements when using this approach to product naming, see section 21.

## Braille Requirements for Name on Product Label

### 20. Legislation

Article 56(a) of Directive 2001/83/EC, as amended, requires that the name of a medicinal product must be expressed in Braille format on the packaging. The name to appear is as referred to in Article 54(a) of the same Directive. Where a medicine is available in more than one strength, these data should also appear in Braille on the label. In some circumstances where different pharmaceutical forms of the same medicine are available with the same name, it is recommended that this information is also included and this will be considered on a case-by-case basis.

	SmPC Section 1	Braille
<b>Required</b>	(Name) + (Strength) + (Pharmaceutical form)	(Name)
<b>Circumstance dependent</b>	N/A	(Strength) and/or (Pharmaceutical form)

### 21. “Short term” on Packaging

Where there are concerns as to the length of the information to appear on the packaging in Braille for products with a long named pharmaceutical form, there is provision for use of the accepted EDQM agreed short term on small packaging. For example, “the short term for “*film coated tablets*” is “*tablets*”. The SmPC guidance states in section 3 that “*The pharmaceutical form should be described by the European Pharmacopoeia full standard term (see section 1). The term used in this section should be the same as the term used in section 1. However, where a European Pharmacopoeia short standard term is used on small immediate packaging material, the short term should be added in brackets in this section.*” For a product with a long named pharmaceutical form, MHRA considers that it is acceptable to use the approved EDQM shortened terms on all packaging as long as this shortened term is included in Section 3 of the SmPC. This applies to both the text of the printed label and the Braille requirements.

Examples of “Short terms” on Packaging:

SmPC Section 1	SmPC Section 3	Name on the label and in Braille
Bloggofen 50mg film coated tablets	Film coated tablets (tablets)	<b>Label:</b> Bloggofen 50mg tablets ibuprofen <b>Braille:</b> Bloggofen 50mg tablets (this assumes there are other strengths of bloggofen available and other pharmaceutical forms)



SmPC Section 1	SmPC Section 3	Name on the label and in Braille
Bloggodex 10mg/ml solution for injection	Solution for injection (injection)	<b>Label:</b> Bloggodex 10mg/ml Injection active substance (INN) strength (50mg in 5 ml) <b>Braille:</b> None (injectable medicine not required)
Bloggopil 10mg hard capsules	Hard capsules (capsules)	<b>Label:</b> Bloggopil 10mg capsules active substance (INN) <b>Braille:</b> Bloggoril (assumes no other strength or form available)
Naproxen 250mg hard capsules	Hard capsules (capsules)	<b>Label:</b> Naproxen 250mg capsules <b>Braille:</b> Naproxen 250mg capsules
Naproxen Bloggo 250mg hard capsules	Hard capsules (capsules)	<b>Label:</b> Naproxen 250mg capsules <b>Braille:</b> Naproxen 250mg capsules

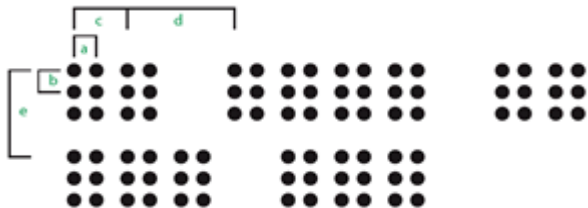
Although discouraged by MHRA because of potential confusion, an applicant is permitted to incorporate the company name or trademark into the name of the medicinal product. Should this naming convention be used, the following labelling and Braille requirements should be noted:

SmPC Section 1	SmPC Section 3	Name on the label and in Braille
Naproxen Bloggo 250mg hard capsule	Hard capsules (capsules)	<b>Label:</b> Naproxen Bloggo 250mg capsules <b>Braille:</b> Naproxen Bloggo 250mg capsules

*Inclusion of a company name within the name of the medicine will not be permitted when there is not sufficient space on the packaging.*

## 22. Marburg Medium Braille Cell Spacing<sup>5</sup>

European guidance has been issued to support the provisions of article 56(a)<sup>3</sup>. The guidance recommends the use of Marburg Medium as the Braille font of choice. The basic Braille symbol is called the Braille cell. Each Braille cell consists of up to six predefined dots set out in two columns of three. The pattern of dots for a given character is defined in the national character set. The Marburg medium spacing convention and dimensions for Braille is illustrated below:



- The dot diameter is 1.6mm;
- The dot spacing is exactly 2.5mm from dot centre to dot centre (a, b);
- The space between two characters is 6.0mm (c);
- The line spacing is 10.0mm (e);
- Word spacing is represented by (d) and is 12.0mm;
- When choosing a name for a medicine it is important to consider how this name will appear on the pack when translated into Braille and to ensure that there is sufficient space on the pack to accommodate the name chosen.

## **Other Considerations**

### **23. MHRA Insistence for an Invented Name**

There are circumstances where MHRA will insist on an invented name rather than a generic name. This is due to the risk to patients from interchanging between products containing the same active constituents but having different bioavailabilities leading to potential differences in therapeutic effects and safety. In such cases it is important that prescribers, pharmacists and patients can readily distinguish between products otherwise having the same drug content. Examples include:

- Prolonged-release products;
- Some locally-acting products;
- Critical care medicines with a narrow therapeutic window of safety and efficacy;
- Alternative generic versions of a product where non-equivalent, branded products are already available on the market;
- Known non-equivalent products available on the market, e.g. those inhaled products where particle size can lead to significantly different therapeutic effects.

### **24. Rejection of an Invented Name**

For a new Marketing Authorisation Application, if the Licensing Authority considers that a product name is not acceptable for reasons of safety or efficacy (as described above), and that the application might therefore have to be refused, the Licensing Authority will seek the advice of the Commission on Human Medicines (CHM) before making a final decision. Normal appeal rights and procedures will apply. Appeal rights apply also to applications submitted as type II variations.

### **25. Right to Appeal**

There are no appeal rights for applications submitted as type IB variations. If MHRA rejects a proposed name submitted via a type IB variation application, the company could resubmit as a new marketing authorisation application for the same product with the proposed new name. Alternatively, a type II variation could be submitted with the proposed new name.

### **26. Pre-submission Advice**

The Agency has procedures for applicant companies to obtain pre-submission scientific advice, which includes advice on safety and efficacy considerations applicable to product names. Should applicants wish to discuss safety or efficacy issues related to product names as part of a scientific advice meeting, they should contact MHRA as per usual procedure.

**Medicines and Healthcare products Regulatory Agency  
December 2009**

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European Medicines Agency December 2007.  
<http://www.emea.europa.eu/pdfs/human/regaffair/032898en.pdf>

**Ref 3:** Guidance concerning the Braille requirements for labelling and the package leaflet,  
European Commission, 2005.  
[http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2005/04\\_05/braille\\_text20050411.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2005/04_05/braille_text20050411.pdf)

**Ref 4:** EDQM list of Standard Terms (subscription required).  
[http://www.edqm.eu/en/Standard\\_Terms-590.html](http://www.edqm.eu/en/Standard_Terms-590.html)

**Ref 5:** Questions and Answers to Address Issues of National Application of the New Provisions  
Concerning Braille on Labelling and in the Patient Information Leaflet of all Medicines,  
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