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Guide to Invented Names of Human Medicines

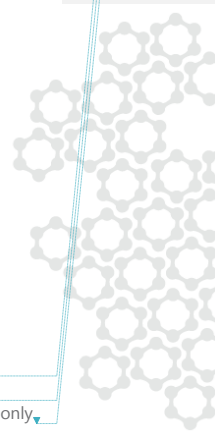
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AUT-G0022-6
07 DECEMBER 2015

This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.



CONTENTS

1	SCOPE	3
2	INTRODUCTION	3
3	GENERAL PRINCIPLES	3
3.1	Possibility of confusion	4
3.2	Misleading inferences	4
4	SPECIFIC ISSUES	5
4.1	Suffixes and prefixes	5
4.2	Umbrella segments	6
4.3	Modified release products	7
4.4	Same active substance for critically-different uses	7
4.5	Other	8
5	PROCEDURE FOR ASSESSING THE ACCEPTABILITY OF NAMES	8
6	MARKETING OF A MEDICINAL PRODUCT FOR BOTH PRESCRIPTION AND NON-PRESCRIPTION SUPPLY	10

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1 SCOPE

The guidance in this document applies to the invented names of prescription and non-prescription medicinal products for human use, authorised by a national, mutual-recognition (MRP) or decentralised procedure (DCP). The guidance does not deal with invented names of products in the centralised procedure or with the presentation of the name, strength and pharmaceutical form on the Summary of Product Characteristics (SmPC), label or package leaflet of a product.

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2 INTRODUCTION

According to Article 1 (20) of Directive 2001/83/EEC, as amended, the name of a medicinal product is defined as 'the name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder'. This name will be stated in section 1 of the SmPC and consequently displayed on the label. It should be followed by its strength and pharmaceutical form in accordance with Articles 11(1), 54(a) and 59(1) (a) of Directive 2001/83/EC, as amended. It is this combination of '(invented) name + strength + pharmaceutical form' that is considered to be the full name of the product. In the context of this document wherever reference is made to 'name' it is understood to mean the full name of the product containing these three elements.

An invented name is the trade name of the product. The common name is the name of the active substance contained in the product; the common name is the INN (International Non-proprietary Name) or, if an INN does not exist, the usual common name.

The invented name is used on the SmPC, labels and package leaflet and in marketing and promotional material. The invented name and its use is the responsibility of the marketing authorisation holder (MAH); the role of the HPRA is to evaluate the acceptability of the name in accordance with the principles outlined below in order to help ensure the safe use of the product.

It should be noted that where a common name is accompanied by the name of the MAH or trade mark, the resulting name should not be promotional or allow a misleading inference.

3 GENERAL PRINCIPLES

A proposed invented name is considered acceptable if there are no perceived public health concerns relating to the possibility of confusion or to misleading inferences.

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3.1 Possibility of confusion

One potential source of medication errors is the possibility of confusion between different products with similar names. Therefore, for reasons of patient safety, a proposed invented name should not be liable to confusion with the invented name of an existing authorised product. The possibility of confusion with an existing name should be considered in print, including Braille, in handwriting and in speech, taking into account such factors as:

- number and position of the common letters,
- number of distinguishing letters (i.e. letters not in common),
- phonetic similarity of letters, and
- use of prefixes or suffixes.

The following factors, which are not exhaustive, should also be considered, bearing in mind the possibility that other pharmaceutical forms, strengths or routes of administration may be introduced for either product in the future:

- pharmaceutical form,
- strength,
- route of administration,
- indications and therapeutic area, and
- method of sale or supply.

A second potential source of confusion arises from similarity between the invented name and the common name of the active substance(s). Article 1 of Directive 2001/83/EEC, as amended, states that the invented name shall not be liable to confusion with the common name. Applicant MAHs are also strongly advised to take account of WHO recommendations that invented names should not be derived from INNs, especially an INN stem, as to do so causes confusion between invented names and INNs and hampers the ability of WHO to devise new INNs (WHO document WHO/EDM/QSM/99.6). A full list of INN stems is available on the WHO website.

3.2 Misleading inferences

Invented names should not be misleading particularly with respect to therapeutic class, therapeutic claims, active substance composition and pharmaceutical connotations. They should not imply therapeutic efficacy for an indication which is not approved nor imply greater efficacy than is justified. The invented name should not highlight a single indication for a product where there is a range of indications approved for that product. Article 87.3 of Directive 2001/83/EC, as amended, requires that advertising of a medicinal product 'shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties' and that it 'shall not be misleading.' This requirement may, by extension, also apply to the invented name of a product, its most potent advertising symbol. Names must be pronounceable.

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4 SPECIFIC ISSUES

4.1 Suffixes and prefixes

Qualification of invented names by letters, numbers or a combination of both should be avoided as they have greater potential than invented names to cause confusion. The use of a new invented name is generally preferable to a single name with a profusion of prefixes and/or suffixes. If a qualification is used, it must be readily-understandable and correctly-interpretable. It should also be meaningful, convey useful information and relate to an important feature of the product. To avoid confusion, a word is preferable to a short one- or two-letter qualifier.

A limited number of suffixes have been accepted to date. Any new suffix which is proposed should be justified and should comply with the general principles listed above. Where a suffix is used to describe the pharmaceutical form, e.g., for modified-release products, it should not cause confusion with the European Pharmacopoeia Standard Term for that form.

It is not considered appropriate to highlight the absence of an excipient or active in the product name (e.g. caffeine-free, colour-free is not acceptable) since it is considered more appropriate to highlight excipients which are part of the formulation.

The suffix 'Forte' or 'Extra Strength' may be acceptable for products with a higher strength of active substance compared with an existing product. However, it should be noted that in line with the requirements of Directive 2001/83/EC as amended, the name on the label and package leaflet must be followed by the actual strength and pharmaceutical form of the product.

The suffix 'Plus' or 'Extra' may be acceptable for products with an additional active compared with an existing authorised product.

For over-the-counter medicinal products, the term 'Maximum' and its abbreviation 'Max' should be included exclusively to denote products containing the maximum permitted content of the active substance per dosage unit, for example, paracetamol 1000mg or ibuprofen 400mg. The reference to 'Max' is also applicable to prescription-only products containing 1000mg of paracetamol.

The prefix 'Co-' may be acceptable for combination products, where an additional active substance is added to an existing product.

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4.2 Umbrella segments

An umbrella segment (also known as root name) of an invented name is a section of invented name that is used for more than one name to create a brand or range of related products. For example: 'Sample Cold & Flu Blackcurrant Powder for Oral Solution' where 'Sample' is the umbrella segment repeated across a related product range. The HPRA strongly encourages applicants to develop new product names **without** umbrella segments for each new product. The proliferation of multiple products with similar but not always identical active substances using connected names may result in confusion among patients or healthcare professionals and possible inappropriate use of these medicinal products.

Umbrella segments of product names may be accepted for products which may be sold without prescription under the following conditions:

- The general therapeutic area for all products with the same umbrella segment should be the same. Where an umbrella segment is 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 products sharing the same umbrella segment.
- The active substance(s) associated with the umbrella segment should be the same, giving due consideration to the underlying general principle of safety. This is particularly pertinent if an umbrella segment has well-understood connotations with respect to its active substance(s). In such cases, that umbrella segment should not be used for a different product where there is a significant difference in active substance(s).
- The umbrella segment should be qualified by a second invented name or by words which specify the particular therapeutic indication and distinguish the product from others in the same range, e.g. 'Sample with decongestant' signifying the presence of a sympathomimetic agent.
- The umbrella segment should be kept as short as possible, taking into consideration the constraints of printing in Braille on product packs. The use of numerous qualifiers in the name should be avoided.
- The umbrella segment should not be used for two related products authorised for supply as prescription only and non-prescription due to the presence of different active substances or different concentrations of an active substance.

The umbrella segment of an existing product name may only be substituted for another umbrella segment where there are no safety concerns. An umbrella segment which is derived from the common name of the active substance(s) may not be used for other products which do not contain that active substance(s).

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Where an umbrella segment is proposed, a documented assessment considering the impact of that name on existing and proposed products with the same umbrella segment in the name should be carried out by the applicant and be made available upon request. The assessment should provide an opinion on why any identified potential risks do not present an actual problem in the proposed market.

Each proposal for a name using an umbrella segment will be considered by the HPRA on a case-by-case basis taking the above concerns into consideration, with safety being the paramount consideration.

4.3 Modified release products

An invented name will normally be required for a modified release or prolonged release product including transdermal dosage forms. Should an MAH not wish to market the product, a 'registration' name using the INN may be acceptable subject to the following conditions:

- a the MAH commits not to market the product using the 'registration' name, and
- b the MAH commits to changing the name to an invented name by way of variation prior to marketing in Ireland.

Each request will be assessed on a case-by-case basis and the conditions as detailed above will be stated in Part 1, section 9 of the schedule to the marketing authorisation.

An invented name will always be required for a modified release or prolonged release product where there is an immediate release product containing the same strength of the same active substance as the modified release or prolonged release product. In certain other cases the INN may be used in place of an invented name if it can be demonstrated that the product can be interchanged safely with other modified release or prolonged release products containing the same active substance (e.g. where bioequivalence has been demonstrated between generic and innovator products). In cases where the INN is proposed as the product name, a succinct justification outlining the reasons for acceptability should be provided with the application (and should not exceed one page in length).

4.4 Same active substance for critically-different uses

Where a medicinal product is proposed to be marketed by a MAH in a critically-different area such as:

- indications and/or contra-indications and/or posology e.g. naltrexone hydrochloride used in alcohol abuse and opioid dependency treatment or reversal of respiratory depression following opioid use in obstetrics;
- patient population e.g. neonates / infants and adults; method of use e.g. oral and parenteral use;

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Serious consideration should be given to applying for separate and distinct marketing authorisations and names.

4.5 Other

A product may be marketed under different invented names (one name per marketing authorisation), so long as there are no public health concerns. While an MAH may submit several proposals for invented names in order of preference, only one name per product can be accepted.

Invented names of discontinued products must not be used for new products which contain a different active substance(s).

Existing invented names should not be used for new products that contain a different active substance(s).

If two (or more) products contain the same active substance but in different salt forms, where **the strength as expressed in the product name refers to the quantity of salt**, then the products should not have the same or similar invented names. For example, if an MAH wishes to market two products where an active substance is present as the sodium salt in product 1 and as the potassium salt in product 2, two distinct invented names would be required. Similarly, any invented name of a generic product of one salt form should not be similar or liable to confusion with any invented names of products containing an alternative salt form(s). If the MAH wishes to use the INN as the product name rather than an invented name, then the product name must include the name of the salt form e.g. 'active substance *sodium* XX mg tablets' rather than 'active substance XX mg tablets'.

Where an invented name of an existing product is used for a replacement product with slightly different active substances or different quantities of those substances, the invented name must include a qualifier to indicate the revised formulation and the new invented name must not be liable to confusion with the name of the original product.

Companies should note that the use of an invented name of a medicinal product for a non-medicinal product, such as a cosmetic, may be misleading and may be in breach of the Medicinal Products (Control of Advertising) Regulations 2007 and the reimbursement rules for the General Medical Services or other community drugs schemes.

5 PROCEDURE FOR ASSESSING THE ACCEPTABILITY OF NAMES

When an assessor considers that an invented name may be unacceptable, the applicant will be informed as early in the assessment procedure as possible, and given the reasons for the objection. The applicant may submit a range of several new proposals for the name or justify the retention of the original name, so that the most suitable name can be approved. As justification for the original name, the registration of the name as a trade mark may not be

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considered as sufficient grounds for accepting the name. Similarly, previous decisions made in relation to product names do not necessarily set precedent in new circumstances. Where the assessor remains of the opinion that the name is unacceptable, an appeal may be made to the HPRA's Management Committee, which may refer the matter for advice to the Advisory Committee on Human Medicines.

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6 MARKETING OF A MEDICINAL PRODUCT FOR BOTH PRESCRIPTION AND NON-PRESCRIPTION SUPPLY

Where permitted by national legislation, an MAH may wish to market a product for both prescription and non-prescription supply. In such cases, MAHs are advised to obtain two authorisations, one for the prescription (reimbursable) and one for the non-prescription product which can be promoted to the public. This is the HPRA's preference, as the two versions are likely to have different pack sizes and/or different indications and thus different labels and leaflets. The products must have different names, though the difference need only be slight and the root brand name may be kept.

Examples of names which have been used and accepted as not giving rise to a safety concern for products with the same composition and concentration but differing in method of sale and supply include:

Prescription-Only (Reimbursable) Product:

- Beconase Aqueous 50 Nasal Spray Suspension
- Zovirax Cream
- Feldene Gel

Non Prescription Product:

- Beconase Hayfever 50 Nasal Spray Suspension
- Zovirax Cold Sore Cream
- Feldene Topigel

Alternately, the MAH may wish to apply for a single marketing authorisation for a product which can be supplied on prescription or over the counter in pharmacies. This option is only possible where the prescription and non-prescription products differ only in pack size, i.e. no difference in therapeutic indications or posology are permitted. Where the MAH obtains a single authorisation for both prescription and OTC 'versions' of a product, and intends to advertise this product, the MAH should be aware of the restrictions imposed by the Medicinal Products (Control of Advertising) Regulations, 2007. Regulation 9 of these regulations prohibits the advertisement of such products to the public. Also, under current Department of Health guidelines for reimbursement and the provisions of Directive 89/105/EEC, a product will not usually be reimbursed if it is advertised to the public.

If the MAH chooses not to advertise the non-prescription version, a single authorisation for both versions may be acceptable but the reimbursement status should be checked with the Health Services Executive. In order to comply with the Medicinal Products (Control of Advertising) Regulations, 2007, the method of sales promotion for the non-prescription version in the authorisation schedule will be to the professions only.

When both prescription and non-prescription supply is requested in one MA application, through the MR procedure, and two authorisations are granted, both authorisations are considered to be within the MR procedure for subsequent variation and renewal applications.

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