HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Invented Names of Veterinary Medicines

1 SCOPE

The guidance in this document applies to the invented names of medicinal products for veterinary use, authorised by a national or mutual-recognition (MR) 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 (SPC), ~~label~~package labelling (immediate and outer) or package leaflet of a product.

2 INTRODUCTION

According to ~~Directive 2001/82/EEC~~Regulation 2019 (EU) 2019/6, the 'name of ~~a~~the veterinary medicinal ~~product is defined as 'the name given to a medicinal product, which may be~~product' means either an invented name not liable to confusion with the common name, or a common or scientific name~~, together with a trade mark~~ accompanied by a trademark or the name of the ~~manufacturer; the invented name shall not be liable to confusion with the common name'~~marketing authorisation holder.

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 one does not exist, the ~~usual common~~ name generally used.

The invented name is used on the SPC, ~~labels and~~ package ~~insert~~labelling and package leaflet and in marketing and promotional material. On the SPC, ~~label~~package labelling and package ~~insert~~leaflet, the invented name is followed by the strength and pharmaceutical form. This guideline only deals with the invented name of the product.

The invented name and its usage is the responsibility of the veterinary product authorisation (VPA) holder; the role of the HPRA is to ensure the acceptability of the name in accordance with the principles outlined below in order to help ensure the safe use of the product.

3 GENERAL PRINCIPLES

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

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 safety, a proposed invented name should not be liable to confusion with the invented name of an existing product.

The possibility of confusion with an existing name should be considered in print, in handwriting and in speech, taking into account:

- the number and position of the common letters,
- the number of distinguishing letters (i.e. letters not in common),
- the 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
- method of sale or supply.

A second potential source of confusion arises with the common name of the active substances. Directive 2001/82/ECRegulation (EU) 2019/6 states that 'thean invented name shall not be 'liable to confusion with the common name'. The World Health Assembly Resolution 46.19 requires the WHO to 'discourage the use of names derived from INNs, and particularly names including INN stems as trade mark.'trademarks. Therefore applicants should not propose names which contain a recognisable fragment of an INN, especially an INN stem, as to do so causes confusion between invented names and INNs and hampers the ability of the WHO to devise new INNs. A full list of INN stems is available on the WHO website.

3.2 Misleading inferences

Invented names should not be misleading with respect to therapeutic class, therapeutic claims, active substance composition or pharmaceutical connotations. They should not imply therapeutic efficacy for an indication which is not approved nor imply greater efficacy than is justified.

4 SPECIFIC NAME ISSUES

4.1 Suffixes

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. If a suffix is used, it must be readily-understandable and correctly-interpretable. The suffix should also be meaningful, convey useful information and relate to an important feature of the product. A word or a long suffix is preferable to a short one- or two-letter suffix.

The suffix 'Forte' or 'Extra Strength' is acceptable for products with a higher strength of active compared with an existing product. However, note that in line with the requirements of Directive 2001/82/ECRegulation (EU) 2019/6, the name must be followed by the actual strength of the product if there is only one active substance.

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

A limited number of suffixes have been accepted to date. Any new suffix which is proposed 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 Ph. Eur. standard term for the form.

4.2 Prefixes

A limited number of prefixes have been accepted. The prefix 'Co-' is acceptable for combination products, where an additional active substance is added to an existing product.

4.3 Umbrella names

Umbrella names (also known as root names) are accepted for products which may be sold without prescription under the following conditions:

a the therapeutic area for all products with the same umbrella name should be the same and
b the umbrella name should be qualified by a second invented name or by words which specify the particular indication and distinguish the product from others in the same range, e.g. suffixes 'lactating cow' or 'dry cow'.

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

4.4 Duplicate products held by one VPA holder

A product may be marketed by a VPA holder under different invented names (one name per Product Authorisation), so long as there are no public health concerns.

4.5 Discontinued products

Invented names of discontinued products must not be used for new products which contain a different active substance. If used for a new product with a slightly different active ~~substances~~substance(s) or quantities of those substances, the invented name must be changed or at the very least, include a qualifier to indicate the revised formulation. The acceptability of the name for the revised formulation will be considered on a case-by-case basis.

5 ASSESSMENT OF THE ACCEPTABILITY OF NAMES

Where the HPRA is concerned that confusion may arise between the proposed invented name and the name of an authorised product or that the proposed name is misleading, the applicant is invited to submit a new proposal for the name or justify the retention of the original name. As justification for the original name, the HPRA does not consider the registration of the name as a trade mark as sufficient grounds for accepting it. Furthermore, if there are grounds for

considering that a proposed name is unacceptable, the HPRA does not consider itself bound to accept a proposed name on the basis of precedent set by other approved names.

HPRA
~~13 February 2013~~
19 July 2022