MHRA

Medicines and Healthcare products Regulatory Agency

Safeguarding public health

MHRA naming policy guideline with respect to umbrella segments of product names

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MHRA NAMING POLICY GUIDELINE WITH RESPECT TO UMBRELLA SEGMENTS OF PRODUCT NAMES

Introduction

1. The purpose of this guideline is to provide industry with guidance on the use of umbrella segments of product names. Notwithstanding the guidance provided below, applications should take into account the principles contained within the best practice guidance on the labelling and packaging of medicines, including prominent display of the active ingredient(s) and pack design/graphics clearly differentiating products (Ref 1) and should conform to the requirements of Directive 2001/83/EC.

2. The product name means the full name stated as in section 1 of the summary of product characteristics and consequently as displayed on the label. It should include the pharmaceutical form and strength when required, in accordance with Directive 2001/83/EC articles 54(a) and 59(1)(a). This name may be an invented name, and may contain a segment regarded as the umbrella, e.g. Bloggofen Cold and Flu Capsules is the name, Bloggofen is the umbrella segment.

3. 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 recognises that it should not impose unnecessary impediments to industry using a particular name, and that other features, such as pack design, labelling etc. can help distinguish between products.

4. The Licensing Authority may reject any name if it considers that, on the information given, or in its own assessment, the name will cause confusion, is misleading, or is otherwise unsafe.

5. Approval 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.

General Principles

6. Directive 2001/83/EC requires that an invented name should not be liable to confusion with the common name. In addition product names, including umbrella segments, should not be misleading with respect to the following:

   - therapeutic effects of the product

- composition of the product
- safety of the product
- confusion of the product with other products with similar names

In the MHRA's view any of the above could raise concerns about the safety of the product.

7. 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 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, or if their speeds of onset are different.

8. Industry is encouraged to give less prominence to the umbrella segment and greater prominence to the active ingredient(s).

Specific Circumstances

9. *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 to 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.

10. *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 than 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).

11. *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 no such association exists, the name should be clearly different to the existing product using where possible the name of the active ingredient.

Factors to be addressed in applications for product names using umbrella segments

12. 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, this guideline proposes that applicants 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 that also considers the impact on existing products sharing the same umbrella segment within their name would facilitate the MHRA consideration of the application. It would be helpful if, as part of the risk assessment, the applicants address how they propose to deal with any potential risks that are identified or explain why, in their opinion, they do not represent 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 application, should the new product 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 between products with the same umbrella segment exist 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_2 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

Other Considerations

13. For an abridged 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 Committee of Safety of Medicines before making a final decision. Normal appeal rights and procedures will apply. Appeal rights apply also to type II variations.

14. If the MHRA rejects a proposed name submitted via a type IB variation application, the company could resubmit an abridged application, for the same product with the proposed new name. If the Licensing Authority proposed to refuse the application, this would then be considered by CSM as above, before reaching a final determination of the application.

15. The Agency has procedures for applicant companies to obtain 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 scientific advice procedures, they should contact the Agency as per usual procedure.

Medicines and Healthcare products Regulatory Agency
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Ref 1: Best Practice Guidance on the labelling and packaging of medicines, Medicines and Healthcare Products Regulatory Agency, December 2002. http://medicines.mhra.gov.uk/inforesources/publications/gn25.pdf