



AESGP MEMBERS' MEETING

THE ACCEPTANCE OF UMBRELLA TRADENAMES IN NATIONAL MARKETING AUTHORISATION PROCEDURES

Federico Plaza Piñol. anefp. 4th February 2009



AGENDA

1. The importance of brands in the industrial context
2. Barriers in Spain
3. Case description: Iniston
4. The recent past
5. The present
6. Europe
7. Conclusions

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The importance of brands in the industrial context

- “Brandnames” are the most valuable asset of the selfcare sector.
- They identify the values and properties that the product represents and they are associated by consumers and health professionals to a known and reliable source.

Concept of umbrella brands

- ***“The use of the same brand name for different non-prescription medicinal products”***(brand product ranges) adding prefixes or suffixes to distinguish one product from another.
- **It allows consumers and pharmacists, to recognise the “product family” and then, select the individual product depending on their needs.**

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Barriers in Spain

- **Pharmaceutical legislation.**

Although it could be considered as a barrier, in fact, the real obstacle is the interpretation of the current legislation.

Article 35 – RD 1345/2007: establishes as a general basis that the name of a medicinal product may not be misleading with respect to the therapeutic properties or nature of the medicinal product

Barriers in Spain

- And....

“the name of the medicine cannot be mistaken for the name of other medicines already on the market.....”

Special mention of “advertisable medicines” establishing that their denominations cannot be the same or cannot be mistaken for medicinal products subjected to medical prescription and/or reimbursed by public funds.

Barriers in Spain

- **Our Health Administration is worried about brands.**
- **I would like to make the following remarks:**
 - **The name of the product is set up to distinguish one product from another and it includes:
brand + pharmaceutical form+ dosage.**
 - **The Brand: includes significant assets that denotes:**

Barriers in Spain

- Brands denote:
 - Quality
 - Belonging
 - Security
 - Service
 - Confidence
 - Loyalty

Spain

- **Pharmaceutical Industry is aware of the concern of Health Administration and so,**
- **in order to ensure:**
 - **the use of umbrella brands (family product range) will not cause any risk to public health**
 - **medicines be taken safely and correctly....**

Spain

....As a result of an agreement between anefp and the Health Administration, a “pilot test” was developed in 2004 to demonstrate that the objections towards umbrella brands were unfounded.

INISTON CASE

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Case description: Iniston

- With the aim to prove that there is no risk of confusion among professionals and consumers
- Iniston pilot test, included not only “brand” but also: pharmaceutical form, basic pack design, colours, and appropriate use of “subbrand elements”(antitussive, mucolytic, descongestant etc...).



Case description: Iniston

- Why Iniston was chosen?
- Because it complied with the requirements established by anefp:
 1. The brand was very well-known
 2. Advertising campaigns in all media mainly on TV were possible by the company
 3. An important point: category competitors were in agreement about the commercial advantage with a view to their own future.

Case description: Iniston

- **Advertising was broadcasted from Nov 04 to Jan 05**
- **The project also included two milestones: a pre-test and post-test of the range, to see whether umbrella branding had mislead consumers.**
- **Two quantitative tests among pharmacists and consumers showing them three packaging and labeling options**
- **One omnibus among spanish population (2.000) after TV campaign.**

Case description: Iniston

- The project was completed successfully, showing that consumers understand perfectly the indications of each type of product.
- Packaging materials work transmitting the indications, and TV advertising facilitates understanding of indications (96% of consumers that recall associate it correctly).

Case description: Iniston

- INISTON TV SPOT:



Case description: Iniston

- Since January 2005 until now no adverse events, no complaints from consumers or pharmacists have been reported.
- More than this...

EVERYBODY IS SATISFIED...

The recent past

-But no other family of products has been approved until now.

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The recent past

- Since 2005, anefp has been demanding clear criteria on the requirements to approve brands (including umbrella brands) → anefp prepared a GUIDELINE meeting the *consensus* of all company members.
- This guideline includes, not only general requirements as regard composition and selection of qualifiers (with some practical examples),
but also:
general limitations for the authorisation brands.

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The present

- **The current opinion of the Spanish Agency is not to take into consideration any practical guidelines.**
- **The umbrella tradenames approval will be developed on a “case by case basis”, only taking into account that the brand doesn’t lead to confusion.**

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Europe

- 1. There aren't any restrictions concerning umbrella brands in the EU pharmaceutical legislation and it is a common practice all around Europe.**
- 2. EU's new pharmaceutical legislation offers to our industry innovative access to the centralised procedure.**
- 3. January 2008: Guideline on the acceptability of names processed through the centralised procedure (rev. 5, paragraph 2.4.4)**

Europe

EMA recognises the specifics of non prescription medicines and considers useful the using of qualifiers (indication, therapeutical activity) to help consumers and professionals in their choice to guarantee and to avoid any risk of confusion.

Some examples of umbrella trade names in Europe



Germany

- Zovirax lippenherpes creme/ **Zovirax**
- Imodium akut , Imodium akut lingual / **Imodium N, Imodium lingual**
- Ibubeta 200 e Ibubeta 400/ **Ibubeta 600 e Ibubeta 800**
- Jenaprofen 200 y Jenaprofen 400 / **Jenaprofen 600 y Jenaprofen 800**



France

- Imodiumlingual/**Imodium**
(*loperamida*)/(*loperamida*)
- Efferalganodis/**Efferalgan**
(*paracetamol*)/(*paracetamol*)
- Efferalganvitaminec/**Efferalgan**
(*paracetamol + vitamina C*/*paracetamol*)

Some examples of umbrella trade names in Europe



Italy

- Voltaren emulgel/**Voltaren, Volteren** ofta
- Zovirax labiale/**Zovirax**
- Feldene cremadol/**Feldene**

• Zovirax 50 mg/g, creme/**Zovirax 200 mg, comprimidos; Zovirax 80 mg/ml, suspensión oral; Zovirax 400 mg, comprimidos; Zovirax 30 mg/g, pomada oftálmica; Zovirax I.V.**



Portugal

• Voltaren emulgel 10 mg/g, gel/**Voltaren 75 mg, comprimidos de liberación prolongada; Voltaren rapid 50 mg, polvo para solución oral; Voltaren 1 mg/ml colirio, solución; Voltaren colirio unidosis 0,3 mg/0,3 ml, colirio, solución**

• Trifene 200 mg comprimidos recubiertos; Trifene 200 mg comprimidos dispersables; Trifene 200 mg comprimidos efervescentes/**Trifene 400 mg comprimidos recubiertos**



United Kingdom

- Zovirax Cold Sore Cream/**Zovirax**
- Zirtek allergy/**Zirtek**
- Benadryl one day allergy/**Benadryl**
- Clarityn Allergy/**Clarityn**
- Beconase allergy/**Beconase**

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Conclusions

- 1. As it is generally recognized**
Medicinal products not subjected to medical prescription have specifics different to other kinds of medicinal products. The main reason for this is that there isn't a medical doctor behind the dispensing, so pharmacists and consumers play the main role.
- 2. Pharmaceutical Industry established in Spain demands a criteria similar to the rest of European countries, taking into account the new environment for the marketing authorisation : (MRP, DCP, CP, National procedure)**
- 3. anefp propose an open dialogue with Spanish Health Authorities to clarify the situation and to reach an agreement in order to see umbrella branding as a reality in the Spanish market as in the rest of Europe.**

THANK YOU VERY MUCH

