

The acceptance of umbrella trade names in national marketing authorisation procedures in Germany

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AESGP-definition

Umbrella trade names: Possibility to use of the same invented name (trade name) for different medicinal products (with different names through suffixes / prefixes but with the same 'core' trade name) which are perceived as treating the same or similar problems (“umbrella trade names” or “umbrella brands”)

(Source: EMEA Hearing on invented names, London, 15 October 2007)

Legal background in Germany

- Drug Act prohibits to manufacture or to market medicinal products which bear misleading product names, specifications or presentations
- BfArM-communication on avoiding misleading names for (Rx and OTC) medicines from August 1991
- Still in force, but influenced by on-going discussions and the guideline on acceptability of invented names ... processed through Centralised Procedure (Dec. 2007)

Principles in Germany

- Invented Names, umbrella trade names and its use is the responsibility of the MAH
- Role of the authorities to evaluate the acceptability of the name to ensure safe use of the product
- Taking into account the specifics of non-prescription medicines (i.e. to help self-selection, to give guidance, trust building etc.)
- Case by case discussions and assessments / decisions

Generally accepted umbrella principles in Germany

- **Same ingredient** with different indications and applications and additional active ingredients ("ancillary")
- **Same therapeutic area** containing same or different active ingredients, different applications
- With different legal status
- If "additional product descriptions" show difference between medicines

⇒ Regulatory chain: Global Marketing Authorisation
(Art. 6 para 1 Dir 2001/83/EC)

OTC umbrella brand example: Aspirin



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OTC umbrella brand example: Voltaren



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OTC umbrella brand example: Vicks



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Conclusion / Germany

- Trademarks and umbrella tradenames are generally accepted
- BfArM-communication and "good practice" gives flexibility ("may", "should be sufficient", "as a rule")
- Well-informed, observant and circumspect (average) consumer is relevant
- Case by case decisions / assessments