

Questions and Answers from Member States
Transfer of product name from originator to generic

Adopted	Status
London, 12 December 2008	Public (Q&A)

QUESTION

A company has existing authorisations of a product with trade name xyz in a range of countries obtained by independent full applications. As a consequence there are differences in the SPCs.

The same company wishes to apply for a registration in the same range of countries and include additional MSs by means of a Community Procedure under Article 13.1 of Directive 2001/82/EC as amended, referring to the said product as registered in one MS. After having obtained the marketing authorisations, can trade name xyz of the originator be transferred to the generic? Do any conditions apply?

ANSWER

Members States can allow a product name to be transferred from the original product to a generic product, however strict conditions apply. Because two products are not allowed to bear the same name either the name of the original product will have to be changed, or the original marketing authorisation will have to be withdrawn.

While the transfer of a name is acceptable in principle, it should be noted that such proposed changes will be considered on a case-by-case basis to ensure that the transfer of product name does not have the potential to cause confusion in the market due to possible differences in SPC between products (for example, with respect to indications, withdrawal periods, etc).