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Question & Answer N. 115/2009

Global marketing and protection period of RP

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QUESTION

Products A, B and C are three VMPs with identical composition and with the same marketing authorisation holder, but they differ in the target species.

Products A and B are registered in one MS and for product A the protection period has expired.

Product C is registered in another MS, still under the protection period.

- 1) Is it possible for a different MAH to register a generic which makes reference to A, B and C as originators even if only for product A the protection period has expired?
- 2) Can A, B and C be considered part of the same global marketing authorisation even if they are registered in different countries (as in the above mentioned situation)?

ANSWER

The CMDv confirms that the concept of global marketing authorisation does apply to products of the same applicant, even if they are authorised in different member states. Therefore, in this specific case, it is possible for the applicant to make reference to products A, B and C even if the protection period has expired just for one of these products, taking into account the period of protection that will be applied by the Member State in which the application is submitted (i.e. 6 or 10 years).