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Question & Answer N. 12/2006

Single generic product with two reference products

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QUESTION

Product A is a pioneer Veterinary Medicinal Product authorised for one target species. Some years later, a product B, identical to product A and with the same Marketing Authorisation Holder, is authorised for another target species. Product B has a different registration number from product A.

1. Taking into account the concept of global marketing authorisation mentioned in the Notice to Applicants (Volume 6A, Chapter 1, Section 2.3) and Article 5 of Directive 2001/82/EC as amended, is it possible for another company to make a single generic product, including both target species, using these two reference products (A and B)?
2. Is the data protection only applicable for product A?

ANSWER

1. Yes, in the scenario described, it is possible to have a single generic product based on two different reference products.
2. Yes, products A and B are considered to be the same product for data protection purposes, and the data protection period will begin from the date of authorisation of product A.