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Question & Answer N. 40a/2007

Data protection generic

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QUESTION

We have an originator product registered for several target species. A few years ago a generic was registered receiving exactly the same SPC as we have for our reference product. Recently, the generic has received a reduction of the withdrawal period for one species, probably by submitting a new residue study.

We would like to apply for the same reduction of withdrawal period. Is there a data protection period for studies submitted by the marketing authorisation holder of the generic product?

ANSWER

Article 13.1 of the Directive 2001/82/EC foresees a period of data exclusivity of ten years for the originator product.

Additional data protection can be granted in situations defined in veterinary pharmaceutical legislation (article 13.1, 13.5 and 13a.3 of the Directive 2001/82/EC) and none of them apply to veterinary generic products.

Therefore CMDv considers that there is no data protection for the residue studies conducted by the marketing authorisation holder of the generic.