

Question & Answer N. 16/2007

Independent national registration with different protection period

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QUESTION

A veterinary medicinal originator has independent national registrations in two countries A and B. Country A has a 6 year protection period and country B a 10 year protection period. Country A grants marketing authorisation for a generic medicinal product.

1. Is it possible to start a MR procedure (RMS = country A, CMS = country B) by claiming reference to the originator in country A before the protection period of the originator in country B expires?

2. Is there a difference if the originator has a marketing authorisation in country A only?

ANSWER

Ad 1. No, this is not possible. Please be referred to the Notice to Applicants, Volume 6A, Chapter 1, 6.1.2, European Commission, November 2005.

Ad 2. Yes. It can be made use of the European Reference product, as long as the data protection where the reference product is approved has expired. Please be referred to the Notice to Applicants, Volume 6A, Chapter 1, 6.1.3, European Commission, November 2005.