



**VETERINARY MUTUAL RECOGNITION  
FACILITATION GROUP (VMRF)**

**QUESTION FROM INDUSTRY  
MRP when two National Authorisations exist**

<b>Adopted</b>	<b>Status</b>
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## QUESTION

A question related to a subsequent mutual recognition procedure (different from a repeat MRP):

A first Mutual recognition procedure was conducted between RMS A and CMS 1, CMS 2 and CMS 3.

The four countries agreed on a SPC text.

Of the same product of the same MAH a national authorisation exists in RMS B. RMS B is willing to defend the dossier in CMS 4, CMS 5 and CMS 6.

Is this possible when the SPC in RMS B is different from the one of the first MRP (RMS A)?

## ANSWER

The Commission provided the following answer:

*“It is then priority of Community legislation to enhance the gradual, continuous and sustained harmonisation of veterinary medicinal products accessing the Community market. Any new application regarding a veterinary medicinal product, which is already covered by an existing marketing authorisation in another Member State should be considered in the context of the Mutual Recognition Procedure. Therefore, Concerned Member States 4, 5 and 6,... , have to be part of the Mutual Recognition Procedure already concluded between Reference Member State A and Concerned Member States 1, 2 and 3.”*