



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

**QUESTION FROM INDUSTRY**

**Withdrawal of an Application During the Validation**

<b>Adopted</b>	<b>Status</b>
October 2003	Public

**QUESTION**

Could VMRFG confirm that during the Mutual Recognition Process, a CMS is not permitted to reject a Marketing Authorisation Application request, at the validation stage, if, by definition, the product in question has been granted Marketing Authorisation by the RMS, on the basis of that same dossier?

**ANSWER**

The VMRFG concluded that in spite of a Veterinary Medicinal Product having been granted a Marketing Authorisation by the RMS it does not mean the CMS will accept the procedure without a validation, and the CMS has the right to validate or reject a Marketing Authorisation application request during the validation stage. The validation process also implies a check of the administrative data which relates to a post authorisation stage (i.e. fee payment, correct compilation of part IA of the dossier, etc.). Therefore it need not necessarily be that an application is to be considered automatically acceptable as a result of the first authorisation. The VMRFG stressed that the validation is always necessary and is a requirement from Member States.