



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

**QUESTION FROM INDUSTRY
Change of Address of the MAH**

Adopted	Status
April 2004	Public

QUESTION

Recently VMRFG took the decision to manage as a national variation the transfer of Marketing Authorisation Holder (Ref : VMRF/190/03- FINAL http://www.hevra.org/documents/specific_issues/FAQ/VMRF_190_03.pdf)with only information of the RMS.

We are facing a change of address of one MAH in one CMS(without impacting other CMS nor RMS). As the change is less important than transfer of responsibility of a MA, could we manage this change also as a national procedure? If variation type IA1 through MRP is mandatory, could we only pay fees in this CMS and inform the other RMS/CMS? As 13 products (including 6 vaccines) are concerned it may represent a very high cost for a very minor local change (which is a big concern for biologicals).

ANSWER

Despite the change of address of one MAH in one CMS having no impact in other CMS, the VMRFG agreed that this is defined as a Type IA variation according to Commission Regulation (EC) No 1084/2003, and must be processed through the Mutual Recognition Procedure. The VMRFG is not in position to advise the applicant regarding fee issues.