



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

QUESTION FROM INDUSTRY

**Application for a Marketing Authorisation on behalf of a Company outside
the EEA by a Regulatory Affairs Consultant**

Adopted	Status
November 2003	Public

QUESTION

Our client is based outside of the EU, and currently does not have an established office, nor a contractual agreement with an EU pharmaceutical establishment. They would like to apply for Marketing Authorisation (MA) for one of their products in an EU Member State, however they would like a Regulatory Affairs Consultancy to act as the applicant on their behalf (who does not have research/manufacturing facilities). In the meantime whilst the regulatory authorities from the Member State are assessing the data they will establish themselves within the EU, either by registering their offices here or by arranging a contractual agreement with a third party. Once the assessment is complete but before a MA is issued, we would like to switch the MAH over to the client company, which by this time will be established in the EU.

ANSWER

Each Member State has to conform to its own national requirements. A harmonised position concerning the possibility for a consultant (in the EEA - European Economic Area i.e. EU, Norway, Iceland and Liechtenstein) to apply for a Marketing Authorisation on behalf of a Company (outside the EEA) could therefore not be reached. According to the requirements of the European legislation, a MAH has to be established in the EU/EEA. Therefore if an applicant who would like to apply for a Marketing Authorisation using a Regulatory Affairs Consultancy (for only one of their products) in an EU Member State from EU, the group suggests that you should contact the relevant national authority.