

## MANDATE FOR BORDERLINE WORKING GROUP

### BACKGROUND

According to Article 31<sup>1</sup> of Directive 2001/82/EC as amended the Veterinary Coordination Group (CMDv) has been established for the examination of any question relating to marketing authorisations of a medicinal product for veterinary use, as defined in the above-mentioned Directive<sup>2</sup>. Moreover, the scope of the directive mentions that in cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'veterinary medicinal product' and within the definition of a product covered by other Community legislation, the provisions of the above mentioned Directive shall apply.

Despite this legal position, it is evident that significant confusion may arise due to differences in interpretation by National Competent Authorities (NCA) and expectations by stakeholders. The borderline product holds an unclear status for regulators, veterinarians, pharmacists, pet keepers, and others. Furthermore there are marked differences between veterinary medicinal products, biocides, and feed additives in terms of data requirements, authorisation procedures, manufacturing requirements, and distribution categories. In addition, the possibility to promote or advertise the product varies depending upon the classification of the product.

Therefore CMDv decided to create a "Borderline Working Group" and give it the following mandate.

### MANDATE

1. To make an inventory of relevant personnel, working groups and teams within National Competent Authorities in order to create a European 'borderline' network.
2. To identify the relevant legislation and the European jurisprudence related to the issue.

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<sup>1</sup> Article 31

A coordination group shall be set up for the examination of any question relating to marketing authorisation of a veterinary medicinal product in two or more Member States in accordance with the procedures laid down in this Chapter.

<sup>2</sup> *Veterinary medicinal product:*

(a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or  
(b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

3. To identify the different areas of borderline products.
4. To agree common understandings between Member States in relation to borderline definitions, in order to minimise any differences in interpretation between Member States.
5. To provide input to CMDv's Legislation Working Group in order to formulate proposals on the development of any revised veterinary Directive.
6. To provide a forum to discuss the classification of a candidate product in order to provide an aid in decision-making to MS in classifying a borderline product.