Appendix 36

REVISION OF THE EUROPEAN PHARMACOPOEIA MONOGRAPH FOR FOOT-AND-MOUTH DISEASE VACCINE AND EUROPEAN GUIDELINES ON REQUIREMENTS FOR FMD VACCINE PRODUCTION

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on behalf of the FAO EUFMD EurPhar Working Group

In the year 2000 the FAO EUFMD EurPhar Working Group was represented at meetings with Group 15V of the EurPhar and with the CVMP/Immunologicals Working Party of EMEA. Based on the discussion at the EurPhar meeting it was proposed that a revision of the FMD Monograph would be prepared by Dr. L. Bruckner. Based on the discussion at the EMEA meeting it was proposed that an ad hoc group would be established to harmonise existing guidelines on FMD vaccine production and control. Prof. PP. Pastoret (Chairman) would prepare the terms of reference of the group. Both documents (added to this report) came available in 2001.

The revision of the FMD Monograph was discussed at a meeting of Group 15V of the EurPhar in Gent-Belgium on June 6, 2001. The EMEA proposal will be discussed on September 19, 2001 in London-UK under the chairmanship of Dr. David MacKay.

The comments of the FAO EUFMD EurPhar Working Group were summarised in a letter addressed to Dr. Bruckner and the EurPhar (added to this report). The comments were then presented at the EurPhar meeting on June 6. During the following four hours discussion the proposed revision was amended (see hand written comments). As a result a new revision proposal will be made by Mr. Castle, Secretary of Group 15V.

The comments of our group were focused on:

The safety test: it was not clear whether or not this was a test to perform once or with every batch. It was made clear by Dr. Bruckner that this was not a batch test.

The batch potency test: The criteria for using an alternative test were unclear. The meeting concluded that there is a need for manufacturers information on the criteria of batch acceptance using an alternative test and for peer reviewed publications covering the criteria used or to be used.

Different FMD strains now and in the future: the meeting referred to future guidelines. EurPhar, FAO and EU will be present at the EMEA meeting.

A monograph for pigs: monographs are published by species. A proposal for pigs will be worked out by Dr. Bruckner in future. This will also be discussed at the meeting organised by EMEA.

Prof. Pastoret proposed to have a discussion with all partners involved: EMEA, OIE, EUFMD, EurPhar, EU, Vaccine manufacturers.

The aim of the meeting would be:
- to review the existing requirements for FMD vaccines from the different organisations;
- to propose draft guidelines on quality, safety and efficacy requirements for FMD vaccine productions as well as for the addition or replacement of FMD strains;
- to discuss the possibility of a marker vaccination programme based on the absence of NS proteins;
- to evaluate the impact of the quasi species status of FMD virus populations.