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CONCEPT PAPER

VACCINES USED FOR VACCINATION AGAINST FOOT AND MOUTH DISEASE

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VACCINES USED FOR VACCINATION AGAINST FOOT AND MOUTH DISEASE

During a recent meeting, the CVMP agreed to set up an ad hoc group under the umbrella of the Immunologicals Working Party on Foot and Mouth Disease (FMD) vaccines with the purpose to harmonise existing guidelines from CVMP, FAO and EDQM. It is proposed that the group would include members of the CVMP/Immunologicals Working Party, FAO, European Pharmacopoeia and OIE with representatives from DG ENTERPRISE and DG SANCO as Observers.

This document therefore describes the current problems with the evaluation of FMD vaccines in Europe and proposes the terms of reference of this group.

THE PROBLEM

The EU and some Member States currently maintain banks of FMD concentrated antigens that can rapidly be formulated into vaccines should a need arise in one or more Member States.

It would obviously be advantageous for FMD vaccines to be evaluated so that the quality, safety and efficacy would be seen to be consistent with Community pharmaceutical legislation and to harmonise the different requirements laid down by EDQM, FAO and OIE with EU regulations.

In addition to policy issues, there are a number of technical issues related to the quality, safety and efficacy of FMD vaccines that have been identified by the concerned organisations.

FMD vaccines present an additional challenge in that any evaluation and authorisation system agreed must be able to permit rapid inclusion of new antigens as new strains of FMD virus may enter European Union territory.

PROPOSAL

It is proposed that a working group is set up with representation from the following organisations:

- The Immunologicals Working Party of the CVMP,
- The OIE,
- The Research Group of the European Commission for the Control of FMD (FAO),
- Group 15V of the European Pharmacopoeia (EDQM, Strasbourg).

Representatives of DG ENTERPRISE and DG SANCO will be invited as Observers. European vaccine manufacturers will be invited to contribute to the work of the Group as and when considered necessary.

The terms of reference of the group would be:

- Review and evaluate the existing requirements for FMD vaccines from the different organisations, in particular to comment on the revised European Pharmacopoeia monograph on inactivated non-oily FMD vaccines for ruminants and on the proposed monograph for oily adjuvanted FMD vaccines and the development of a safety and efficacy tests in pigs;

- Define the necessary steps for harmonised EU requirements;

- Propose to the CVMP, through the IWP, draft guidelines on quality, safety and efficacy requirements for standardised production of FMD vaccines. This should cover all aspects from choice and production of the vaccine strain to formulation of finished product of the vaccine from concentrated antigens;

- Include within a draft CVMP Guideline the requirements for addition or replacement of new antigens in an existing vaccine.

- Define the quality, safety and efficacy requirements necessary for a FMD vaccine to be used within the framework of a marker vaccination program based on the absence of NS proteins;

- Evaluate the impact, if any, of the quasi species status of FMD virus populations.