

Strasbourg, 17-18 March 2003

# *Foot and Mouth Disease*

International symposium organised  
by the EDQM, Council of Europe,  
Strasbourg

Scientific Programme

Working language: English



## Monday, 17 March 2003

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### *Session I: Introduction (i.e. background to the need for a meeting)*

9:00

#### **Current regulatory and scientific background**

- Background to the meeting
  - CVMP draft guideline
  - Revision of EU FMD legislation
  - Revision of Ph. Eur. monograph
- Objectives of the meeting

Mr Peter Castle, Secretary to the European Pharmacopoeia Commission, EDQM, Council of Europe

9:30

#### **Proposal for EDQM reference sera**

Mr Jean-Marc Spieser, Head of Division IV, EDQM, Council of Europe

9:45

#### **Viewpoint and perspectives of the Office International des Epizooties (OIE)**

- What the current requirements for FMD vaccines are in the OIE Manual
- Why more/updated guidance is now needed
- Changes in FMD code that make "vaccination to live" a more acceptable policy
- Implications of proposed CVMP guidelines for FMD vaccine quality worldwide

Dr Alejandro Schudel, Office International des Epizooties (OIE, F)

- Discussion: 10 min

10:30

#### **Coffee Break**

11:00

#### **Viewpoint and perspectives of the Food and Agriculture Organization (FAO)**

- Why FAO supports development of guidelines for FMD vaccines
- What are the implications of uptake of CVMP guidelines for EUFMD Commission Members

Dr Kris De Clercq, CODA-CERVA-VAR Epizootic Diseases Section (B)

- Discussion: 10 min

11:45

#### **European Legislation: Viewpoint and perspectives**

- What criteria does the Commission intend to apply for FMD antigens in the EU vaccine bank
- How does the Commission propose to react to the changes in the OIE code
- Commission stance and proposals/possibilities for change in EU pharmaceutical legislation to promote authorisation of FMD vaccines

Invited speaker from the European Commission, DG Sanco/E2 (B) (to be confirmed)

and Dr Anne Gautrais, European Community DG Entreprise (B)

- Discussion: 10 min

12:30

#### **Lunch Break**

# MOUTH DISEASE

## *Session II: Requirements for a «Modern» FMD vaccine: quality aspects to be dealt with*

**14:20** Requirements for authorisation of foot-and-mouth disease vaccines within the European Union  
Dr David Mackay, Veterinary Medicines Directorate (VMD, UK)

- Discussion: 10 min

**15:05** The Ph. Eur. monograph for FMD vaccines  
• Do we need an additional monograph for vaccines for pigs?  
• Do we need reference sera?  
Dr Lukas Bruckner, Institut für Viruskrankheiten und Immunoprophylaxis (IVI, CH)

- Discussion: 10 min

**15:45** Production of EDQM reference sera  
Mr Jean-Marc Spieser, Head of Division IV, EDQM, Council of Europe

- Discussion: 5 min

**16:00** Alternatives to the challenge test: serological assays and small animal models  
Dr Paul Barnett, Institut for Animal Health, Pirbright Laboratory (IAH, UK)

- Discussion: 10 min

**Potency testing, an industrial perspective**  
Dr Tim Doel, Merial Animal Health Ltd (UK)

- Discussion: 10 min

**16:45** Coffee break

**17:15** Quality requirements for a “vaccination to live” policy  
• Non-Structural proteins (NSP) as markers of infection  
• Quality requirements for vaccines  
• Requirement for companion diagnostic tests  
• Current state of the art  
• Future prospects  
Dr Paul Van Aarle, Intervet International BV (NL)

**Validation of assays used in FMD control programmes: a continuously frustrating process**  
Dr John Crowther, International Atomic Energy Agency (IAEA, A)

- Discussion: 10 min

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*Session III: Requirements for a «Modern» FMD vaccine: efficacy aspects to be dealt with*

9:00

**Practical implication of a “vaccination to live” policy**

- Policy for procurement of antigens, vaccines and diagnostic tests
- Contingency planning for mass serology
- The “exit strategy”

Invited speaker from the UK Department of Environment, Food and Rural Affairs (DEFRA)

- Discussion: 10 min

9:40

**The carrier state of foot-and-mouth disease in ruminants - current knowledge and prospects for vaccination or cure**

Prof. Soren Alexandersen, Institute for Animal Health, Pirbright Laboratory (IAH, UK)

- Discussion: 10 min

10:20

**Coffee Break**

10:50

**New approaches to control foot-and-mouth disease**

Dr Marvin Grubman, Plum Island Animal Disease Center (USA)

- Discussion: 10 min

11:30

**Modelling the economic impact of FMD - from farm to national level impact**

- An overview of studies on the economic impact of FMD
- The importance of including farm-level economic impact assessment for FMD and its control
- Modelling the economic impact of FMD and its control in extensive beef systems - the case of Bolivia
- Modelling the economic impact of FMD in the livestock systems of the UK
- How to improve economic assessments of FMD and its control
- Potential economic impact of improved vaccines

Dr Jonathan Rusthon, CEVEP (Bolivia)

- Discussion: 10 min

*Session IV: Round table discussion: requirements for change*

12:10

to 13:00

**Round table discussion and conclusions**

Proposals in CVMP position paper, requirements for changes in EU legislation, requirements for future research in relation to vaccines, requirements for reference sera and other reagents

*Representatives from the European Pharmacopoeia, the European Commission, the OIE and Regulatory authorities*



**Organisation**

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