Strasbourg, 17-18 March 2003

Foot and Mouth Disease

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

Scientific Programme

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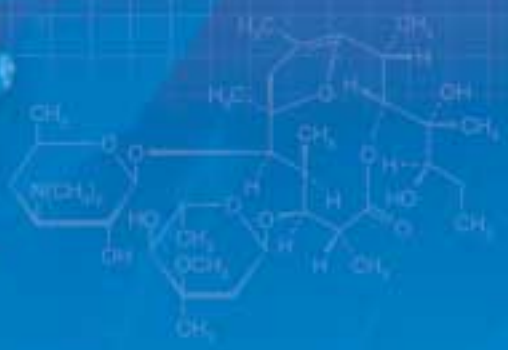

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

FOOT AND

Programme

Monday, 17 March 2003

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

Tuesday, 18 March 2003

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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