The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines and Information Technology

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**MEETING REPORT OF THE
SEVENTH EMEA/FEDESA JOINT INFODAY
AT THE EUROPEAN AGENCY IN LONDON**

The seventh joint EMEA/FEDESA Infoday was held at the Agency in London on 18-19 May 2000 entitled '**European Authorisation Procedures and Medicines Availability: Now and the Future**' and covered a range of issues, including Medicines Availability, the 2001 Review of Medicines Regulations, the Efficiency of the Centralised and Mutual Recognition Systems, International Harmonisation and Antimicrobial Resistance. Dr Peter Jones, Head of Veterinary Medicines and Information Technology Unit at EMEA said in his opening remarks that the Infoday was critically important in providing the first opportunity for European regulators and industry to exchange views on the Audit 2001 review of the Regulatory Procedures in the EU. He also welcomed the publication of two reports to be reviewed at the meeting on the efficiency of the two regulatory procedures, centralised and mutual recognition, which were both very positive, but wherein opportunities for improvement would be highlighted.

The Availability of Medicines continues to be one of the greatest areas of concern in the veterinary sector and all speakers expressed some disappointment that greater progress had not been achieved. The European Task Force on Availability has succeeded in keeping attention focussed on the real issues and there was encouragement to progress the initiatives to provide derogations under Council Directive 81/851/EEC, to certain minor species of food animals, especially the horse, to allow authorisation of medicines without MRLs provided suitable withdrawal periods are applied. Participants were also appreciative of the initiative undertaken by the EMEA in preparing a proposal for an Orphan Drug policy on veterinary medicines. The report by Professor Friis, chair of the CVMP ad hoc group on Risk Analysis, that CVMP had adopted earlier the same day a new guideline for consultation – supporting the possibility of a wider extrapolation of MRLs from one species to another or – under certain conditions – to all food producing species was well received. Prof. Friis said "these recommendations are sound based on the wealth of data available to the Committee having completed the evaluation of the safety of residues for over 700 substances and do not compromise consumer safety.

The session on the Audit 2001 of European Regulatory Systems resulted in a vigorous debate as anticipated. Dr Brigitte Boenisch from FEDESA indicated that industry saw this as a unique opportunity to improve the current systems. She reaffirmed industry's call for a free choice of registration procedures for all products, centralised or mutual recognition. Industry also requests recognition of the legitimate needs of the animal health industry separate from those of the human sector when changes are considered in designing future systems. The EMEA summarised its reflections for the 2001 review emphasising the critical need for an ongoing partnership with Member States to optimise both the centralised and mutual recognition, but reminding participants that any changes must continue to consolidate the single market in pharmaceuticals and maximise the protection of human and animal health. The challenges of an expanded Community to possibly 28 Member States would mean considerable changes to the current structures in order to find systems that were robust enough to achieve the goals of these systems in the years ahead. A representative of the Portuguese Presidency representing the Member States stated that "The competent authorities from the fifteen Member States and the EMEA (with the Commission) have to preserve the extraordinary "acquis" build up during recent years, evolving from the current situation to greater levels of efficacy in the co-operation mechanisms". "Furthermore the future should reserve a stronger place for the co-

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operation of the Member States as drivers of the system in close co-operation with the EMEA and help from Commission and Parliament".

During the Infoday a major milestone was reached when representatives of industry, the Member States and the EMEA presented summaries of the two first reports prepared jointly by FEDESA with EMEA and VMRFG on the performance of the centralised and mutual recognition systems respectively during 1999 and 2000. Whilst it was acknowledged that both systems are working well and effectively, improvements are possible and all parties are committed to optimising efficiency, and continuing these surveys.

The remaining session on Current Important Topics provided an informative update on expansion to Central and Eastern European Countries, VICH, and CVMP activities on Antimicrobial Resistance. In the first paper Professor Alfred Hera from the Institute for State Control of Veterinary Biologicals and Medicaments, Czech Republic gave an in-depth report of the preparations underway in the candidate countries in readiness for accession to the European Union. Professor Alfred Hera stated that "most if not all countries have adopted and implemented Community legislation in pharmaceuticals, but it is difficult to estimate the extent of the implementation because of the different types of regulatory systems in place". His paper provided results of a detailed questionnaire completed by countries concerned as to the extent of progress made. Dr Susanne Zänker from FEDESA was enthusiastic in summarising the significant advances achieved by VICH in just under 4 years, in progressing almost 20 guidelines to harmonise the diverse testing requirements existing between the major parties EU, USA and Japan and reviewed future plans.

A presentation by Dr Steve Dean, CVMP member from the UK, on the CVMP's Risk Management Strategic Plan on Antimicrobial Resistance resulted in some vigorous discussion. Different views were expressed by participants on the best means of containing resistance, but there was common understanding on the need to develop guidelines on pre-authorisation sensitivity testing to predict resistance development as proposed in the Strategic Plan. The plan will also aim to ensure a scientifically sound approach to the determination of MICs when assessing the pharmacokinetic properties of antimicrobials to facilitate the definition of indications and posology.

Copies of proceedings and the joint reports on the Centralised and Mutual Recognition Procedures are available from Dr Susanne Zänker at FEDESA (techsec@fedesa.be).

Thursday 18 May

13:30	Registration for Info day	
14:00	Welcome and Introduction	***Peter Jones, EMEA***

The Availability Issue **Chairperson: Annika Wennberg,**

14:05	In Veterinary Practice – What's happening?	*Fred Nind, FVE*
14:25	European Task Force – Goals and Achievements	*Kornelia Grein, EMEA*
14:45	The Commission – Are we making progress?	*To be confirmed*
15:00	Risk Assessment for MRLs – A New Approach	*Christian Friis, CVMP, DK*
15:20	Panel Discussion	
15:45	Tea break	

Veterinary Medicines – 2001 Review **Chairman: Jean Weissenberger, Commission, DG ENTERPRISE**

16:15	Veterinary Regulation 2000 - An Industry Perspective	*Brigitte Boenisch, FEDESA*
16:35	The Agency Viewpoint	*Peter Jones, EMEA*
16:55	Member States - What Do They Think	*Prof. Rogério Gaspar, PO*
17:15	Questions & Discussions	
18:00	Reception	
19:00	Buffet Supper at EMEA. Dinner speaker:	*Pierre Choraine, Executive Director, FVE*

Friday 19 May

Important developments: An update **Chairperson: Peter Jones, EMEA**

09:00	Harmonisation and Interpretation of EU Guidelines in CADREAC Countries	*Prof. A. Hera, CZ State Control Lab*
09:15	VICH: Progress and challenges?	*Susanne Zänker, FEDESA*
09:40	Antimicrobial Resistance: CVMP Approach to Risk Management	*Steve Dean, CVMP, UK*
10:00	Discussion	
10:30	Coffee break	

European Regulatory Procedures **Chairman: Ghislain Follet, FEDESA**

Centralised Procedures – Joint Survey

11:00	EMEA/CVMP Perspective	*Jill Ashley-Smith, EMEA*
11:20	FEDESA Perspective	*Rick Clayton, FEDESA*
11:40	Discussion	
12:00	From Validation to SPC – The Lessons Learned	*Melanie Leivers, EMEA*
12:20	Questions	
12:30	Lunch	

Mutual Recognition Procedure - Joint Survey

14:00	Introduction to the Joint VMRFG/FEDESA survey	*Carlos Sinogas, Infarmed, PO*
14:30	FEDESA's perspective	*Jim Bell, FEDESA*
14:50	Member States' Perspective	*Gerard Moulin,* AFSSA, France
15:10	Discussion	
15:30	Close	

LIST OF ATTENDEES

EMEA/FEDESA Info Day
European Authorisation Procedures and Medicines Availability: Now and the Future

Name	***Organisation***	***Country***
Mr Stephen Adams	Huntingdon Life Sciences Ltd	United Kingdom
Ms Maxine Ainslie	Schering Plough Animal Health	United Kingdom
Mr Guy Appleby	Elanco Animal Science Research	United Kingdom
Dr Jill Ashley-Smith	EMEA (European Agency for the Evaluation of Medicinal Products)	United Kingdom
Dr David Baldwin	Fort Dodge Animal Health	Belgium
Dr Rhona Banks	Fort Dodge Animal Health	United Kingdom
Mr James Bell	Intervet International GmbH	Germany
Ms Caroline Belmont	Boehringer Ingelheim Ltd	United Kingdom
Dr Brigitte Boenisch	Merial	France
Dr Marie-Anne Botrel	EMEA (European Agency for the Evaluation of Medicinal Products)	
Ms Annie-Claude Bouvier	Ceva Sante Animale	France
Ms Joan Brooks		United Kingdom
Dr Jutta Büchner	IDT GmbH	Germany
Ms Mary Jane Carter	Boehringer Ingelheim Vetmedica GmbH	Germany
Ms Mireille Chaton – Schaffner	Ceva Sante Animale	France
Dr Pierre Choraine	FVE	Belgium
Mr Rick Clayton	FEDESA	Belgium
Dr Malcolm Cobb	Leo Animal Health Ltd	United Kingdom
Ms Brigitte Colin	Vetoquinol	France
Mr Roger Cook	NOAH	United Kingdom
Mr Paul E Cooper	Merial	United Kingdom
Mr Bob Cornez	Janssen Animal Health BVBA.	Belgium
Ms Gillian Cowan	Intervet International BV	
Dr Jaques Cuvelier	Virbac	France
Dr Barbara Cyrus	EMEA (European Agency for the Evaluation of Medicinal Products)	United Kingdom

Name	***Organisation***	***Country***
Dr Roger R Dawson	COPA-COGECA	United Kingdom
Mr Stephen Dawson	NOAH	United Kingdom
Mr Gert De Beckker	Pharmacia & Upjohn	Belgium
Mr Steve Dean	Veterinary Medicine Directorate	United Kingdom
Ms Paula Dominguez Salas	FEDESA	Belgium
Ms Isaura Duarte	EMEA (European Agency for the Evaluation of Medicinal Products)	United Kingdom
Ms Merel Dubbelaar	FEDESA	Belgium
Dr Sabine Eglit	BgVV	Germany
Mr Lionel F Elsom	Huntingdon Life Sciences Ltd	United Kingdom
Ms Françoise Falize	Ministere Sante Publique & Environnement	Belgium
Dr Jean Claude Fedou	Ceva S.A.	Hungary
Mr Birthe Finderup	Schering Plough AH	Denmark
Mr Andrew Fleetwood	Pfizer Central Research	United Kingdom
Dr Ghislain Follet	Pfizer Animal Health	Belgium
Ms Barbara Freischem	EMEA (European Agency for the Evaluation of Medicinal Products)	United Kingdom
Prof Christian Friis	Royal Veterinary And Agricultural University	Denmark
Dr Rogério Gaspar	Faculdade De Farmacia	Portugal
Dr Evelyne Gassmann	Novartis Animal Health Inc	Switzerland
Ms Flora Giorgio	GPUE - Groupement Pharmaceutique de l'Union Européenne	Belgium
Mr Markus V Graf	Novartis	Switzerland
Ms Audrey Green	Irish Medicines Board	Ireland
Ms Kornelia Grein	EMEA (European Agency For The Evaluation Of Medicinal Products)	United Kingdom
Ms Valérie Guiral-Treuil	Merial	France
Dr Raymond Harding	Cyton Biosciences Ltd	United Kingdom
Mr Gareth Harris	Boehringer Ingelheim Vetmedica GmbH	Germany
Dr Marie-Odile Hendrickx	Pfizer Central Research	United Kingdom
Dr Alfred Hera	Institute For State Control Of Veterinary Biologicals And Medicaments	Czech Republic
Dr Dirk Hoerstermann	Boehringer Ingelheim Vetmedica GmbH	Germany
Dr Eliane Honig	Intervet International B.V.	The Netherlands

Name	***Organisation***	***Country***
Mr Jean Louis Hunault	SIMV	France
Dr David Hurd	Vetoquinol UK Ltd	United Kingdom
Dr Kirsten Jacobsen	Pharmacia Animal Health Nordic Area	Denmark
Dr Ulrich Jänicke	Bayer AG	Germany
Dr Peter Jones	EMEA (European Agency for the Evaluation of Medicinal Products)	United Kingdom
Dr Katarina Kivilahti	National Agency for Medicines	Finland
Dr Victor Knox	Inveresk Ltd	Northern Ireland
Dr Kristina Lehmann	National Agency for Medicines	Finland
Ms Melanie Leivers	EMEA (European Agency for the Evaluation of Medicinal Products)	United Kingdom
Mr David Lewis	Pfizer Central Research	United Kingdom
Dr Hervé Marion	FEDESA	Belgium
Dr Ashok Mehta	Schering Plough Animal Health	United Kingdom
Dr Marta Leonor Meisel	INFARMED	Portugal
Ms Marylin Mitchelson	Elanco Animal Science Research	United Kingdom
Prof Manfred Moos	Paul-Ehrlich-Institut	Germany
Mr Gérard Moulin	ANMV - AFSSA	France
Dr Anthony Mudd	COMISA	Belgium
Mr Jesper Mygind	VIF	Denmark
Mr Fred Nind	UEVP	United Kingdom
Mr John O'Brien	Veterinary Medicines Directorate	United Kingdom
Mr Declan O'Brien	Apha	Ireland
Dr Metod Ostanek	Lek Animal Health	Slovenia
Mr Roger Parker	Schering Plough Animal Health	United Kingdom
Mrs Wendy Parker	EMEA (European Agency for the Evaluation of Medicinal Products)	United Kingdom
Prof Paul-Pierre Pastoret	Universite de Liege	Belgium
Dr Margarida Maria Pratas	IPPAA-CNPCZ	Portugal
Dr Tony Price	Schering Plough Animal Health	United Kingdom
Dr Leena Raesaenen	Ministry of Agriculture and Forestry	Finland
Mr Ramzan Ramzan Visanji	Intervet	United Kingdom
Ms Emmanuelle Royer	Merial	France
Dr Eva Schmidt	Intervet International Gmbh	Germany
Dr Sabine Schüller	Bayer AG	Germany
Prof Carlos Sinogas	INFARMED	Portugal
Ms Isabel Sobral	INFARMED	Portugal

Name	***Organisation***	***Country***
Mr Ferdy Sprangers	Algemene Farmaceutische Inspectie	Belgium
Mr Adrian Steward	Novartis Animal Health Uk Ltd.	United Kingdom
Ms Isabelle Toussaint	Novartis Sante Animale	France
Dr Bruno Urbain	Ministry of Health	Belgium
Dr Peter C Van der Valk	Fort Dodge Animal Health	The Netherlands
Mr Jan van der Weide	Merial	France
Dr William Vandaele	Bvd Consultants S.A.	Belgium
Dr L. Vingiani	AISA	Italy
Dr John Walters	Elanco Animal Health	United Kingdom
Dr Jean Weissenberger	European Commission - DG Enterprise	Belgium
Dr Annika Wennberg	Medical Products Agency	Sweden
Dr Kevin Woodward	Schering Plough Animal Health	United Kingdom
Dr Suzanne Zänker	FEDESA	Belgium