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

London, 19 April 2002
EMEA/CVMP/417/02

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS
76th MEETING

Under the Chairmanship of Mr G. Moulin the seventy sixth meeting of the Committee for Veterinary Medicinal Products took place in London on 16 – 18 April 2002.

CVMP Opinions on Medicinal Products

The Committee unanimously adopted 1 positive opinion and CVMP assessment report for a recombinant vaccine against Infectious Bursal disease and Marek's disease in chickens, namely Gallivac HVT IBD and a positive opinion and CVMP assessment report for an extension for a further species (cats) for Metacam 5 mg/ml solution for injection.

The Committee unanimously adopted 2 positive opinions and CVMP assessment reports for 2 Type II variations on TSE compliance and quality aspects, respectively regarding 1 immunological and 1 pharmaceutical product previously assessed under the centralised procedure.

Establishment of Maximum Residue Limits

The Committee unanimously adopted 3 positive opinions and summary reports recommending the modification of the MRLs for ceftiofur in bovine species, the extension of the Annex II entry for xylazine hydrochloride to dairy cows and the inclusion in Annex II of hydroxyethyl salicylate for all food producing species except fish.

Further to the request of the Commission to re-consider the ADI previously established for abamectin in light of the new data considered by JECFA and JMPR, the CVMP adopted a Summary Report establishing an increased ADI for abamectin (150µg/person)

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	**44**	**17**	**2**
New MRL procedures[1]	**115**[2]	**4**	**6**

[1] Applications submitted to the EMEA after 01.01.1995
[2] Including 17 Opinions recommending definitive MRLs for substances with previously provisional MRLs

Public

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.eu.int http://www.emea.eu.int

Guidelines, SOPs and Position Papers

The Committee endorsed a revised list of substances considered as not falling within the scope of Council Regulation (EEC) No 2377/90 to include casein hydrolysate and collagen hydrolysate used as excipients (EMEA/CVMP/046/00-Rev.3).

Pharmacovigilance issues

Periodic Safety Update Reports (PSURs) on 4 centrally authorised products were considered by the Committee. The Committee concluded that the information available did not create a need for further action or changes to the respective Summary of Product Characteristics (SPC).

The Committee agreed on a harmonised warning regarding inadvertent self-injection for inclusion in the SPC and the product literature for veterinary medicinal products containing mineral oils. It is intended that these warnings will be included in the guideline for Summary of the Product Characteristics.

The Committee endorsed the preliminary programme for a joint EMEA/FEDESA/FVE workshop on veterinary pharmacovigilance in the EU to be held in Spain during their presidency and welcomed this initiative on this important topic (document attached).

International Harmonisation

The Committee adopted a recommendation for the preparation of the CVMP/EU contribution to the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) to be submitted to the European Commission.

The Committee was informed of the outcome of the PERF II Conference held in Tallinn, Estonia, and acknowledged the significant progress achieved by the candidate countries in preparing for accession in the veterinary pharmaceutical sector and was also informed of ongoing issues to be addressed in PERF III (document attached).

Organisational Issues

The Committee adopted the meeting dates for 2004 (EMEA/CVMP/224/02-FINAL)

The next meeting of the CVMP will be held on 14-16 May 2002

Peter G.H. Jones
Head, Veterinary Medicines Evaluation Unit
This press release and other documents are available on the Internet at the following address:
http://www.emea.eu.int

Maximum Residue Limits for New Substances adopted by the Community since January 2000

Substance a) INN	**Therapeutic area** a) Target species	**EMEA/CVMP** a) Validation b) Opinion c) Active time d) Clockstop	**Commission** a) Sent to Commission b) Date of the regulation c) OJ No.
a) Bismuth subnitrate (extension)	a) Bovine	a) 18.06.99 b) 13.10.99 c) 113 days d) 0	a) 12.11.99 b) 19.06.00 c) OJ No. L 145 of 20.06.00
a) Acetyl isovaleryl tylosin tartrate	a) Porcine	a) 18.10.95 b) 13.10.99 c) 195 days d) 1260 days	a) 12.11.99 b) 19.06.00 c) OJ No. L 145 of 20.06.00
a) Methylprednisolone	a) Bovine	a) 13.07.99 b) 13.10.99 c) 92 days d) 0	a) 12.11.99 b) 19.06.00 c) OJ No. L 145 of 20.06.00
a) Deltamethrin (extension)	a) Fin fish	a) 09.12.99 b) 08.03.00 c) 90 days d) 0	a) 07.04.00 b) 15.09.00 c) OJ No. L234 of 16.09.00
a) Tylosin (extension)	a) Eggs	a) 09.11.99 b) 08.03.00 c) 90 days d) 0	a) 07.04.00 b) 15.09.00 c) OJ No. L234 of 16.09.00
a) Dicyclanil	a) Ovine	a) 25.02.97 b) 08.03.00 c) 281 days d) 825 days	a) 07.04.00 b) 15.09.00 c) OJ No. L234 of 16.09.00
a) Tilmicosin (extension)	a) Rabbit	a) 16.07.99 b) 13.10.99 c) 86 days d) 0	a) 12.11.99 b) 20.10.00 c) OJ No. L269 of 21.10.00
a) Flumequine (extension)	a) Bovine milk & turkey	a) 27.07.99 b) 10.11.99 c) 89 days d) 0	a) 09.12.99 b) 20.10.00 c) OJ No. L269 of 21.10.00
a) Tiamulin (extension)	a) Rabbit	a) 14.10.99 b) 12.01.00 c) 90 days d) 0	a) 11.02.00 b) 20.10.00 c) OJ No. L269 of 21.10.00
a) Dicyclanil (modification)	a) Sheep fat	a) 23.02.00 b) 17.05.00 c) 84 days d) 0	a) 16.06.00 b) 27.10.00 c) OJ No. L276 of 28.10.00
a) Butafosfan (extension)	a) Dairy cattle	a) 19.01.00 b) 19.04.00 c) 90 days d) 0	a) 19.05.00 b) 27.10.00 c) OJ No. L276 of 28.10.00
a) Tilmicosin (extension)	a) Bovine milk	a) 22.02.99 b) 19.04.00 c) 203 days d) 210 days	a) 19.05.00 b) 27.10.00 c) OJ No. L276 of 28.10.00

Substance a) INN	**Therapeutic area** a) Target species	**EMEA/CVMP** a) Validation b) Opinion c) Active time d) Clockstop	**Commission** a) Sent to Commission b) Date of the regulation c) OJ No.
a) Phoxim (extension)	a) Ovine	a) 19.01.00 b) 19.04.00 c) 90 days d) 0	a) 19.05.00 b) 27.10.00 c) OJ No. L276 of 28.10.00
a) Flumethrin (extension)	a) Ovine	a) 19.01.00 b) 19.04.00 c) 90 days d) 0	a) 19.05.00 b) 27.10.00 c) OJ No. L276 of 28.10.00
a) Flunixin (extension)	a) Equidae	a) 23.03.00 b) 21.06.00 c) 90 days d) 0	a) 21.07.00 b) 29.12.00 c) OJ No. L336 of 30.12.00
a) Toltrazuril (extension)	a) Porcine	a) 16.02.99 b) 21.06.00 c) 206 days d) 284 days	a) 21.07.00 b) 29.12.00 c) OJ No. L336 of 30.12.00
a) Halofuginone	a) Bovine	a) 10.12.96 b) 21.06.00 c) 281 days d) 1008 days	a) 21.07.00 b) 29.12.00 c) OJ No. L336 of 30.12.00
a) Difloxacin (extension)	a) Bovine, Porcine	a) 14.07.98 b) 21.06.00 c) 205 days d) 503 days	a) 21.07.00 b) 29.12.00 c) OJ No. L336 of 30.12.00
a) Linear dodecyl benzene sulfonic acid	a) Bovine	a) 22.01.99 b) 19.07.00 c) 195 days d) 321 days	a) 18.08.00 b) 25.04.01 c) OJ No. L118 of 27.04.01
a) Phoxim (extension)	a) Ovine	a) 19.01.00 b) 19.07.00 c) 120 days d) 0	a) 18.08.00 b) 25.04.01 c) OJ No. L118 of 27.04.01
a) Florfenicol (extension)	a) Fin fish	a) 29.10.96 b) 11.10.00 c) 212 days d) 1230 days	a) 08.11.00 b) 29.06.01 c) OJ No. L177 of 30.06.01
a) Meloxicam (extension)	a) Porcine	a) 07.09.00 b) 06.12.00 c) 90 days d) 0	a) 04.01.01 b) 27.06.01 c) OJ No. L175 of 28.06.01
a) Tilmicosin (extension)	a) Turkey	a) 07.09.00 b) 06.12.00 c) 90 days d) 0	a) 04.01.01 b) 27.06.01 c) OJ No. L175 of 28.06.01
a) Doramectin (extension)	a) Reindeer	a) 11.12.97 b) 10.01.01 c) 203 days d) 923 days	a) 09.02.01 b) 18.07.01 c) OJ No. L195 of 19.07.01
a) Rafoxanide	a) Bovine, ovine	a) 11.02.97 b) 10.01.01 c) 193 days d) 1236 days	a) 09.02.01 b) 18.07.01 c) OJ No. L195 of 19.07.01

Substance a) INN	**Therapeutic area** a) Target species	**EMEA/CVMP** a) Validation b) Opinion c) Active time d) Clockstop	**Commission**) Sent to Commission b) Date of the regulation c) OJ No.
a) Tiludronate	a) Equine	a) 12.10.00 b) 10.01.01 c) 90 days d) 0	a) 09.02.01 b) 18.07.01 c) OJ No. L195 of 19.07.01
a) Moxidectin (extension)	a) Bovine milk	a) 09.10.00 b) 14.02.01 c) 90 days d) 0	a) 16.03.01 b) 30.07.01 c) OJ No. L205 of 31.07.01
a) Tosychloramide Sodium (extension)	a) Bovine	a) 20.01.00 b) 14.03.01 c) 120 days d) 298 days	a) 06.04.01 b) 22.08.01 c) OJ No. L227 of 23.08.01
a) Bronopol (extension)	a) Salmonidae	a) 15.03.01 b) 13.06.01 c) 90 days d) 0	a) 06.07.01 b) 07.11.01 c) OJ No. L291 of 08.11.01
a) Deltamethrin (extension)	a) Fin fish	a) 09.11.99 b) 13.06.01 c) 177 days d) 404 days	a) 06.07.01 b) 07.11.01 c) OJ No. L291 of 08.11.01
a) Methylprednisolone	a) Bovine	a) 13.07.99 b) 11.07.01 c) 177 days d) 535 days	a) 02.08.01 b) 17.01.02 c) OJ No. L16 of 18.01.02
a) Acetylisovaleryltylosin (extension)	a) Bovine	a) 12.04.01 b) 11.07.01 c) 84 days d) 0	a) 03.08.01 b) 17.01.02 c) OJ No. L16 of 18.01.02

Veterinary Medicinal Products that have been granted a Community marketing authorisation since January 2000

Product a) Brandname b) INN c) Part A/B	**Company** a) Name b) Origin	**Therapeutic area** a) Target species b) Indication	**Presentation** a) Form b) Dosage c) No. of presentations	**EMEA/CVMP** a) Validation b) Opinion c) Active time d) Clockstop	**Commission** a) Opinion received b) Decision c) Notification d) OJ No.
a) Ibraxion b) Inactivated vaccine c) Part A	a) Merial b) FR	a) Cattle b) Vaccine against IBR	a) Emulsion for injection	a) 17.11.98 b) 10.11.99 c) 210 days d) 176 days	a) 10.12.99 b) 09.03. 00 c) 10.03. 00 d) OJ No. C 95 of 04.04.2000
a) Metacam b) Meloxicam c) Part B extension	a) Boehringer Ingelheim b) DE	a) Dogs b) Alleviation of pain and inflammation	a) Oral suspension b) 1.5 mg/ml c) 3	a) 12.01.99 b) 10.11.99 c) 210 days d) 92 days	a) 10.12.99 b) 24.03.00 c) 27.03.00 d) OJ No. C 120 of 28.04.00
a) Metacam b) Meloxicam c) Part B extension	a) Boehringer Ingelheim b) DE	a) Dogs b) Initiation therapy for alleviation of pain and inflammation	a) Solution for injection b) 5 mg/ml c) 1	a) 12.01.99 b) 10.11.99 c) 210 days d) 92 days	a) 10.12.99 b) 24.03.00 c) 27.03.00 d) OJ No. C 120 of 28.04.00
a) Incurin b) Oestriol c) Part B	a) Intervet b) NL	a) Dogs b) Hormone-dependent urinary incontinence	a) Scored tablets b) 1 mg c) 1	a) 14.07.98 b) 08.12.99 c) 210 days d) 302 days	a) 07.01.00 b) 24.03.00 c) 29.03.00 d) OJ No. C 120 of 28.04.00
a) Rabigen SAG2 b) Live vaccine c) Part A	a) Virbac b) FR	a) Foxes b) Vaccine against rabies	a) Liquid within a blister pack embedded in a bait b) 8 log 10 CCID50 c) 2	a) 23.03.98 b) 08.12.99 c) 196 days d) 428 days	a) 07.01.00 b) 06.04.00 c) 10.04.00 d) OJ No. C 120 of 28.04.00
a) Eurifel FeLV b) Live vaccine c) Part A	a) Merial b) FR	a) Cats b) Vaccine against feline leukaemis	a) Pellet + diluent b) 1 ml c) 3	a) 12.01.99 b) 08.12.99 c) 183 days d) 120 days	a) 07.01.00 b) 13.04.00 c) 18.04.00 d) OJ No. C 120 of 28.04.00
a) Porcilis Pesti b) Inactivated vaccine c) Part A	a) Intervet b) NL	a) Pigs b) Marker vaccine against CSF	a) Water in oil emulsion b) 120 Elisa Units/2ml c) 3	a) 14.07.98 b) 13.10.99 c) 210 days d) 246 days	a) 12.11.99 b) 09.06.00 c) 14.06.00 d) OJ No. C 183 of 30.06.00
a) Ibaflin b) Ibafloxacin c) Part B	a) Intervet b) NL	a) Dogs b) Pyoderma	a) Tablet b) 150 & 300mg c) 1	a) 12.01.99 b) 09.02.00 c) 210 days d) 184 days	a) 10.03.00 b) 13.06.00 c) 15.06.00 d) OJ No. C 183 of 30.06.00
a) Metacam b) Meloxicam c) Part B extension	a) Boehringer Ingelheim b) DE	a) Dogs b) Post-operative pain	a) Solution for injection b) 5mg/ml c) 1	a) 02.01.00 b) 19.04.00 c) 101 days d) 7 days	a) 28.04.00 b) 15.09.00 c) 18.09.00 d) OJ No. C 277 of 29.09.00
a) Econor b) Valnemulin c) Part B extension	a) Novartis b) AT	a) Pigs b) Prevention & treatment of dysentery	a) 0.5% premix b) various c) 2	a) 10.08.99 b) 19.04.00 c) 210 days d) 43 days	a) 19.05.00 b) 15.09.00 c) 20.09.00 d) OJ No. C 308

Product a) Brandname b) INN c) Part A/B	**Company** a) Name b) Origin	**Therapeutic area** a) Target species b) Indication	**Presentation** a) Form b) Dosage c) No. of presentations	**EMEA/CVMP** a) Validation b) Opinion c) Active time d) Clockstop	**Commission** a) Opinion received b) Decision c) Notification d) OJ No.
					of 27.10.00
a) Econor b) Valnemulin c) Part B extension	a) Novartis b) AT	a) Pigs b) Prevention /treatment of dysentery and treatment/control of enzootic pneumonia	a) 10%/50% premix b) various c) 2	a) 12.10.99 b) 08.03.00 c) 148 days d) 0	a) 07.04.00 b) 15.09.00 c) 20.09.00 d) OJ No. C 308 of 27.10.00
a) Econor b) Valnemulin c) Part B extension	a) Novartis b) AT	a) Pigs b) Prevention /treatment of dysentery and treatment/control of enzootic pneumonia	a) 10%/50% premix b) various c) 2	a) 12.10.99 b) 08.03.00 c) 148 days d) 0	a) 07.04.00 b) 15.09.00 c) 22.09.00 d) OJ No. C 308 of 27.10.00
a) Dicural b) Difloxacin c) Part B extension	a) Fort Dodge Animal Health b) NL	a) Cattle & Dogs b) Antibacterial for systemic use	a) Solution for injection b) 50 mg/ml c) 3	a) 16.12.98 b) 21.06.00 c) 203 days d) 351 days	a) 21.07.00 b) 24.10.00 c) 25.10.00 d) OJ No. C 337 of 28.11.00
a) Porcilis AR-T-DF b) Inactivated vaccine c) Part A	a) Intervet b) NL	a) Pigs b) Vaccine against atrophic rhinitis	a) Suspension for injection b) 2 ml c) 2	a) 12.01.99 b) 19.07.00 c) 204 days d) 336 days	a) 18.08.00 b) 13.11.00 c) 20.11.00 d) OJ No. C 2 of 05.01.01
a) Poulflox b) Difloxacin c) Part B	a) Virbac S.A. b) FR	a) Poultry b) Antibacterial for systemic use	a) Oral solution b) 100 mg/ml c) 3	a) 09.12.99 b) 21.06.00 c) 152 days d) 43 days	a) 21.07.00 b) 16.11.00 c) 20.11.00 d) OJ No. C 2 of 05.01.01
a) Pruban b) Resocortol butyrate c) Part B	a) Intervet b) NL	a) Dogs b) Anti-inflammatory for cutaneous inflammatory disorders	a) Cream b) 1 mg/ml c) 1	a) 15.09.98 b) 19.07.00 c) 196 days d) 477 days	a) 18.08.00 b) 16.11.00 c) 20.11.00 d) OJ No. C 2 of 05.01.01
a) Pirsue b) Pirlimycin c) Part B	a) Pharmacia b) BE	a) Dairy cattle b) Subclinical mastitis	a) Sterlie solution b) 5 mg/ml c) 4	a) 12.01.99 b) 11.10.00 c) 210 days d) 428 days	a) 10.11.00 b) 29.01.01 c) 31.01.01 d) OJ No. C 53 of 20.02.01
a) Bayovac CSF E2 b) Live vaccine c) Part A	a) Bayer b) DE	a) Pigs b) Marker vaccine against classical swine fever	a) Emulsion for injection b) E2 glycoprotein of (CSF) virus c) 4	a) 16.12.98 c) 08.11.00 c) 210 days d) 309 days	a) 29.11.00 b) 02.02.01 c) 06.02.01 d) OJ No.C 53 of 20.02.01
a) Zubrin b) Tepoxalin c) Part B	a) Schering-Plough b) UK	a) Dogs b) Treatment of pain and inflammation	a) Oral lyophilisate b) 30, 50, 100 & 200 mg/ml c) 39	a) 18.05.99 b) 08.11.00 c) 210 days d) 330 days	a) 08.12.00 b) 13.03.01 c) 14.03.01 d) OJ No. C 127 of 27.04.01
a) Eurican Herpes 205	a) Merial b) FR	a) Dogs b) Vaccine against	a) Powder + solvent for	a) 13.07.99 b) 08.11.00	a) 08.12.00 b) 26.03.01

Product a) Brandname b) INN c) Part A/B	**Company** a) Name b) Origin	**Therapeutic area** a) Target species b) Indication	**Presentation** a) Form b) Dosage c) No. of presentations	**EMEA/CVMP** a) Validation b) Opinion c) Active time d) Clockstop	**Commission** a) Opinion received b) Decision c) Notification d) OJ No.
b) Inactivated vaccine c) Part B		canine herpes	emulsion for injection b) 1 ml c) 2	c) 209 days d) 274 days	c) 29.03.01 d) OJ No. C 127 of 27.04.01
a) Metacam b) Meloxicam c) Part B extension	a) Boehringer Ingelheim b) DE	a) Cattle b) Diarrhoea / respiratory infections	a) Solution for injection b) 20 mg/ml c) 2	a) 14.09.99 b) 10.01.01 c) 184 days d) 301 days	a) 09.02.01 b) 23.04.01 c) 25.04.01 d) OJ No. C 158 of 31.05.01
a) Virbagen Omega b) Feline interferon c) Part A	a) Virbac S.A b) FR	a) Dogs b) Reduce mortality and clinical signs of canine parvovirosis	a) Solution for injection b) 5MU/ml or 10MU/ml c) 1	a) 21.12.99 b) 11.07.01 c) 210 days d) 358 days	a) 10.08.01 b) 06.11.01 c) 08.11.01 d) OJ No. C 336 of 30.11.01

Further information is available on Maximum Residue Limits adopted by the Community and Veterinary Medicinal Products that have been granted a Community Marketing Authorisation in the EMEA General Report 2000 on the Internet at the following address: http://www.emea.eu.int.

EMEA[1]/CVMP[2]/FEDESA[3]/FVE[4] and Veterinary Faculty of the Complutense University of Madrid

Workshop on the Veterinary Pharmacovigilance System in the EU

When:
27-28 May 2002 (afternoon jointly with HEVRA)

Where:
Spain: Madrid

Aim:
How to promote the veterinary pharmacovigilance system.

PRELIMINARY PROGRAMME

Chair of the meeting
Professor Arturo Anadón,
Head of the Department of Toxicology and Pharmacology, Complutense University, Madrid (Spain) and President of EAVPT

Day 1

13.00	**Registration of participants**
13.45	**Welcome Address** **Prof. Dr. Manuel Rodriguez Sanchez, Dean of the Veterinary Faculty**
14.00 – 14.20	Pharmacovigilance – Are we fulfilling our Obligations? **P. Jones, EMEA**
14.20 – 14.50	How does it operate in EU – Member States perspective **A. Holm, DK – G. Keck, F**
14.50 – 15.10	How does it operate – EMEA perspective **K. Grein, EMEA**
15.10 – 15.30	Industry – Report as little as possible vs what is adequate **D. Sutton, FEDESA**
15.30 – 15.50	Discussion
15.50 – 16.00	**Coffee break**
16.00 – 16.20	Does the veterinary profession support the reporting concept? **F. Nind, FVE**

[1] EMEA European Agency for the Evaluation of Medicinal Products
[2] CVMP Committee for Veterinary Medicinal Products
[3] FEDESA European Federation of Animal Health
[4] FVE Federation of Veterinarians of the EC

16.20 – 16.40 The animal owner – could care less?
Breeder/Farmer Association

16.40 – 17.00 Marketing Pharmacovigilance
T. Kamphuis, NL

17.00 – 17.45 Discussion

Day 2

Chair of the meeting
- representative from Authorities: **C. Evans*/A. Gray*, UK**
- representative from FEDESA: **D. Sutton, FEDESA**

08.30 – 08.50 Role of the authorities – How are cases collected?
C. Ibrahim, DE

08.50 – 09.10 Pharmacovigilance guidelines – harmonisation let's go: VICH
D. O'Rourke, FEDESA

09.10 – 09.25 Electronic reporting and the right way to present: An Introduction, incl. VEDDRA
S. Brosch, EMEA

09.25 – 09.40 Chairman: Introduction to Break-out sessions

09.40 – 10.00 **Coffee break**

10.00 – 12.30 **Breakout sessions**

Workshop 1: Ideal reporting scheme
Chair: E. De Ridder, FEDESA
Rapporteur:

Workshop 2: Handling of cases and analysis
Chair: B. Freischem, EMEA
Rapporteur:

Workshop 3: How can we promote pharmacovigilance?
Chair: T. Kamphuis, NL
Rapporteur:

12.30 – 14.00 **Lunch**

14.00 – 15.30 Report from each workshop session and Discussion

15.30 – 16.30 **General Discussion and Conclusions**

16.30 **Closure of the workshop and Coffee**

* *pending confirmation*

2nd Conference of the Pan – European Regulatory Forum On Pharmaceuticals (PERF)

April 3-5, 2002
Tallinn, Estonia

Overall Conclusions of the Veterinary Topics

PERF II Veterinary Topics
Rapporteur's Report: Acquis

Upgrading Dossiers

Many of the Candidate Countries (CC's) are well advanced in upgrading dossiers (mostly in connection with renewal process)

Some of the countries have still not replied to the questionnaires

- status of activities therefore unknown
- maybe indicative of little or no progress
- continuing effort required for next Acquis workshops

Discussions firmly reinforced the need for compliance with hard law for standalone dossiers,dependent dossiers and referrals

ACQUIS continued

Phasing In

Clear progress in the centralised system where 7 countries indicated a number of centrally approved products authorised in CC's

In the Mutual Recognition Procedure little evidence of progress made in voluntary harmonisation although many of the products licensed in EU are authorised in CC's but quality of these dossiers maybe in question

ACQUIS continued

Some Critical Issues

Complete implementation of legislation in some countries has still to be finalised and further training must then follow on:

- well established use
- authorisation of generics
- need further hands-on experience of MRP

Industry have real concerns re costs of upgrading dossiers, because market size is unattractive and there is little return on investment

Confidentiality is still a major concern but being addressed

Labelling in all new official EU languages: call for flexibility?

Likelihood of major availability problem: Prediction from CC companies of a loss of 30% of products

AQUIS continued

Critical Issues continued

- However the primacy of consumer safety is recognised and acknowledged that update will rightly result in higher quality products
- Considerable debate on the provisions of Article 7 of Directive 2001/82:
  "***However where the health situation so requires, a Member State <u>may</u> authorize the placing on the market or administration to animals of veterinary medicinal products which have been authorised by another Member State in accordance with this Directive"***
- "*the health situation*" in its broadest interpretation will likely be the Availability of Medicines issue and participants wish further to discuss the application of this article in some depth

ACQUIS continued

e.g.s of Further Critical Issues

Can the Veterinary medicinal product in the CC be the subject of well established use?

Does the definition of constituents apply to active ingredients and excipients because the Directive is not clear on these points

Borderline Products

- There is wide variation in the CC's on what constitutes borderline products and it will be extremely difficult to get agreement
- Biocides Directive in EU is finalised but lack of agreement by Member States for a guideline on this topic continues to be problematical
- Some Member States have their own Guidelines

  e.g Irish Medicines Board www.imb.ie
- Consultation with the VMRFG can be very useful and is strongly recommended
- Commission cannot give further guidance and these products have to be treated on a case by case basis

Medicated Premixes-Feed Additives

- Feed Additives not authorised under pharmaceutical law in EU are licensed as veterinary medicines in most CC's, e.g antibiotic growth promoters and anticoccidials
- Participants were informed of the new proposed Regulation for Feed Additives under consideration by Parliament and Council
  - ban remaining antimicrobial growth promoters
  - anticoccidials remain as feed additives
  - includes water medication
- Transition for feed legislation appears to be slow so progress to declassify these products from status before accession must be progressed

Safety of Veterinary Medicines

- Consumer Safety satisfactorily addressed
- Breakthrough in provision of analytical methods by industry to monitor compliance with MRL's – pending assurances on mechanisms to ensure confidentiality*
- New developments in environmental safety testing highlighted (post phase II VICH guideline)
- CVMP Risk Management Strategic Plan for minimising antimicrobial resistance considered in some depth and its implications considered with likely consequences for authorisation of antimicrobials and their prudent use
- Availability of Medicines issues discussed (ongoing theme throughout) and in particular the cascade and its advantages and (?disadvantages)

*(Training at laboratory level identified as a need)

Pharmacovigilance in Veterinary Medicines

- Transposition of EU Law into National Law has progressed well
- Implementation of Community Law and application of Guidelines is very heterogeneous.
- Participants well recognise the need to make Pharmacovigilance an active living process (it has to be marketed!)
- The support of the veterinary profession, the farming community and animal owners in imperative (whilst not strictly within criteria of PERF – EU law; further initiatives have to be considered
- Secondments have proved very valuable and need to be considered futher with agreement from MS
- The whole issue achieves greater significance if proposals in the Review to remove renewals goes ahead

Veterinary Immunologicals

- Good progress has been made on this topic for assessment purposes
- Official Batch Release was discussed in some detail and the Commission is seeking to address the setting up of necessary mechanisms to facilitate a joint agreement by Member States
- Further training is recognised as important for compliance with TSE Guidelines and ensuring adherence for those products authorised in CC's
- Procedures for compliance with Directive 90/220 for biotech products must be addressed further

Market Authorisation Procedures

Generally good progress has been made and this work is seen as approaching completion

However further training is recognised as being helpful in several areas

- proposals for changes in Review 2000 and their impact on the CC's
- assessor training and guidance in preparing assessment reports (Quality,Safety &Efficacy)
- new EU guidelines that evolve prior to accession

Harmonisation of SPC's is a challenge that meets with limited enthusiasm, but recognised as facilitating the economic feasibility for marketing products in the CC's

The simplified procedure for centrally approved products now documented and to be presented to next CAVDRI "assembly"

Veterinary Efficacy Requirements

- Good progress made to date with workshops held to-date
- Translation of European Guidelines is an issue to address by CC's at next Acquis meeting
- Identified some further areas of training in the use and interpretation of EU guidelines for CC's
- Maybe some further work to do on Antimicrobial Resistance following further developments at CVMP