The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines Evaluation Unit

London, 11 December 1998
EMEA/CVMP/622/98

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS
38th MEETING

Under the chairmanship of Professor R. Kroker the thirty-eighth meeting of the Committee for Veterinary Medicinal Products took place in London on 8 - 10 December 1998.

Opinions

- The Committee adopted an Opinion and CVMP Assessment Report in respect of a bovine concentrated lactoserum containing immunoglobulins against the *E. Coli* F5 (K99) adhesin, and falling under Part A of the Annex to Council Regulation (EEC) No. 2309/93.

- The Committee agreed Opinions for 2 old substances (both recommendations for Annex III of Council Regulation (EC) No. 2377/90). The Committee also adopted Opinions for 5 substances used in veterinary homeopathic therapy in concentrations higher than 1:10 000 (recommendations for Annex II).

- Further to appeals received from companies, the Committee decided that revised MRLs could be set for 1 new substance and also that an entry in Annex II for 1 old substance could be recommended.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	**12**	**12**	**10**
MRL procedures*	**42****	**18**	**12**

* Applications submitted to the EMEA after 1.1.1995
** including 2 Opinions recommending definitive MRLs for substances with previously provisional MRLs

Appointment of Rapporteurs

- The Committee appointed a Rapporteur and a Co-Rapporteur for a Veterinary Medicinal Product falling under Part B of the annex to Council Regulation (EEC) No. 2309/93.

- The Committee appointed Rapporteurs for applications under the MRL procedure (for 1 full, 3 extensions and 1 modification) for three new substances.

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Notes for Guidance

The Committee adopted the following Note for Guidance for release for consultation for 6 months:

- Note for Guidance for the determination of withdrawal periods for milk (EMEA/CVMP/473/98- CONSULTATION).

The Committee adopted the following Notes for Guidance for release for consultation for 5 months following approval at VICH Steering Committee at Step 4:

- Note for Guidance on environmental impact assessment (EIAS) for veterinary medicinal products – Phase I (EMEA/CVMP/592/98)
- Note for Guidance on the efficacy on anthelmintics: General requirements (EMEA/CVMP/593/98)
- Note for Guidance on the stability testing for medicated premixes (EMEA/CVMP/594/98)
- Note for Guidance on good clinical practices (EMEA/CVMP/595/98)
- Note for Guidance on impurities in new veterinary drug substances (EMEA/CVMP/596/98)
- Note for Guidance on impurities in new veterinary medicinal products (EMEA/CVMP/597/98)

The Committee adopted the following Notes for Guidance following the close of the consultation period and following approval at the VICH Steering Committee at Step 7:

- Note for Guidance on validation of analytical procedures: Definition and terminology (EMEA/CVMP/590/98)
- Note for Guidance on validation of analytical procedures: Methodology (EMEA/CVMP/591/98)

The implementation date for both Notes for Guidance is October 1999.

Miscellaneous Items

- Following the Committee meeting, the fifth joint FEDESA/EMEA Info-Day was held on 11 December 1998. The Info-Day was dedicated to Immunological Veterinary Medicinal products and covered the following topics:
    - Critical aspects of regulatory Requirements
    - New trends in veterinary vaccines, including biotechnologically derived vaccines
    - The achievements of the CVMP Immunologicals Working Party
    - A review of current guidelines
    - Current developments in Community vaccination policy
    - Global standardisation and Harmonisation of testing requirements
    - Compliance with European Pharmacopoeia monographs
    - Batch release requirements and
    - MRL requirements for excipients used in vaccines

  Further details are presented in the accompanying Summary

- The next meeting of the CVMP will be held on 12-14 January 1999.

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.eudra.org/emea.html

Maximum Residue Limits for New Substances adopted by the Community since 1.1.1995

(Status: December 1998)

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) Difloxacin	a) Chicken, turkeys	a) 16.05.95 b) 15.12.95 c) 134 days d) 49 days	a) 13.02.96 b) 08.07.96 c) OJ No. L 170 of 09.07.96
a) Ketoprofen (extension)	a) Porcine	a) 15.05.95 b) 22.03.96 c) 85 days d) 217 days	a) 25.04.96 b) 06.09.96 c) OJ No. L 226 of 07.09.96
a) Diclazuril	a) Ovine	a) 12.12.95 b) 24.04.96 c) 104 days d) 0	a) 24.05.96 b) 21.10.96 c) OJ No. L 269 of 22.10.96
a) Eprinomectin	a) Bovine	a) 22.02.96 b) 25.06.96 c) 108 days d) 0	a) 26.07.96 b) 08.01.97 c) OJ No. L 5 of 09.01.97
a) Doramectin (modification)	a) Bovine	a) 14.05.96 b) 24.07.96 c) 70 days d) 0	a) 23.08.96 b) 14.02.97 c) OJ No. L 45 of 15.02.97
a) Praziquantel	a) Ovine	a) 03.08.95 b) 18.09.96 c) 187 days d) 152 days	a) 16.10.96 b) 25.04.97 c) OJ No. L 110 of 26.04.97
a) Moxidectin (modification)	a) Bovine and Ovine	a) 12.06.96 b) 18.09.96 c) 97 days d) 0	a) 16.10.96 b) 25.04.97 c) OJ No. L 110 of 26.04.97
a) Difloxacin (modification)	a) Chicken, Turkeys	a) 10.07.96 b) 23.10.96 c) 104 days d) 0	a) 19.11.96 b) 25.04.97 c) OJ No. L 110 of 26.04.97
a) Ivermectin (extension)	a) Deer	a) 20.08.96 b) 11.12.96 c) 86 days d) 0	a) 09.01.97 b) 23.04.97 c) OJ No. L 106 of 24.04.97
a) Amitraz (extension)	a) Bees	a) 18.10.96 b) 12.02.97 c) 115 days d) 0	a) 12.03.97 b) 24.09.97 c) OJ No. L 263 of 25.09.97
a) Doramectin (extension)	a) Swine and Ovine	a) 10.06.96 b) 12.02.97 c) 118 days d) 127 days	a) 12.03.97 b) 24.09.97 c) OJ No. L 263 of 25.09.97
a) Cefazolin (extension)	a) Ovine and Caprine	a) 05.06.97 b) 10.09.97 c) 97 days d) 0	a) 10.10.97 b) 16.01.98 c) OJ No. L 11 of 17.01.98

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) Isoflurane	a) Equine	a) 13.05.96 b) 07.05.97 c) 200 days d) 158 days	a) 05.06.97 b) 23.02.98 c) OJ No. L 53 of 24.02.98
a) Teflubenzuron	a) Fish	a) 20.01.97 b) 07.05.97 c) 105 days d) 0	a) 05.06.97 b) 23.02.98 c) OJ No. L 53 of 24.02.98
a) Florfenicol (extension)	a) Fish	a) 29.01.96 b) 16.07.97 c) 129 days d) 404 days	a) 12.08.97 b) 18.03.98 c) OJ No. L 82 of 19.03.98
a) Moxidectin (extension)	a) Equidae	a) 09.04.97 b) 16.07.97 c) 96 days d) 0	a) 12.08.97 b) 18.03.98 c) OJ No. L 82 of 19.03.98
a) Praziquantel (extension)	a) Equidae	a) 15.09.97 b) 14.01.98 c) 120 days d) 0	a) 09.02.98 b) 27.05.98 c) OJ No. L 154 of 28.05.98
a) Meloxicam	a) Bovine	a) 28.03.96 b) 11.06.97 c) 212 days d) 229 days	a) 09.07.97 b) 17.07.98 c) OJ No. L 205 of 22.07.98
a) Tilmicosin (extension)	a) Chicken	a) 14.07.97 b) 12.11.97 c) 111 days d) 0	a) 12.12.97 b) 09.09.98 c) OJ No. L 250 of 10.09.98
a) Valnemulin	a) Porcine	a) 02.08.96 b) 06.05.98 c) 207 days d) 641 days	a) 05.06.98 b) 27.11.98 c) OJ No. L 320 of 28.11.98
a) Alfaprostol (extension)	a) Rabbits	a) 15.05.97 b) 06.05.98 c) 200 days d) 362 days	a) 05.06.98 b) 27.11.98 c) OJ No. L 320 of 28.11.98
a) Rifaximin	a) All mammalian food producing species	a) 09.01.97 b) 06.05.98 c) 180 days d) 508 days	a) 05.06.98 b) 27.11.98 c) OJ No. L 320 of 28.11.98

Maximum Residue Limits for Old Substances adopted by the CVMP and the Community

(Status: December 1998)

TOTAL 444			
Annex I	Annex II	Annex III	Annex IV
52	339	42	11
Published in the Official Journal of the European Communities: **352**			

Veterinary Medicinal Products that have been granted a Community marketing authorisation under the centralised procedure

(Status: December 1998)

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) Nobi-vac-Porcoli b) Inactivated vaccine c) Part A	a) Intervet International b) NL	a) Piglets b) Neonatal colibacillosis	a) Solution for injection b) Multidose c) 2	a) 01.01.95 b) 27.07.95 c) 107 days d) 94 days	a) 24.08.95 b) 29.02.96 c) 04.03.96 d) OJ No. C96 of 29.03.96
a) Pentofel b) Vaccine c) Part A	a) Fort Dodge Laboratories b) IRL	a) Cats b) Rhinotracheitis	a) Solution for injection b) Monodose c) 3	a) 16.06.95 b) 18.09.96 c) 208 days d) 235 days	a) 17.10.96 b) 05.02.97 c) 06.02.97 d) OJ No. C63 of 28.02.97
a) Quadrisol b) Vedaprofen c) Part B	a) Intervet International b) NL	a) Horses b) Control of inflammation	a) Oral gel b) 100mg/ml c) 1	a) 07.05.96 b) 16.07.97 c) 209 days d) 235 days	a) 14.08.97 b) 04.12.97 c) 05.12.97 d) OJ No. C392 of 24.12.97
a) Metacam b) Meloxicam c) Part B	a)Boehringer Ingelheim b) DE	a) Cattle b) Adjunctive therapy in acute respiratory infection	a) Solution for injection b) 5mg/ml c) 1	a) 24.06.96 b) 16.07.97 c) 208 days d) 180 days	a) 14.08.97 b) 07.01.98 c) 08.01.98 d) OJ No. C32 of 30.01.98
a) Dicural b) Difloxacin c) Part B	a) Fort Dodge Animal Health b) NL	a) Poultry b) Antibacterial for systematic use	a) Oral solution b) 100mg/ml c) 2	a) 06.12.95 b) 11.06.97 c) 218 days d) 337 days	a) 11.07.97 b) 16.01.98 c) 20.01.98 d) OJ No. C63 of 27.02.98
a) Clomicalm b) Clomipramine c) Part B	a) Ciba-Geigy b) FR	a) Dogs b) Treatment of anxieties	a) Tablets b) 5, 20 and 80mg c) 3	a) 13.11.96 b) 12.11.97 c) 210 days d) 156 days	a) 12.12.97 b) 01.04.98 c) 02.04.98 d) OJ No. C126 of 24.04.98
a) Neocolipor b) Inactivated vaccine c) Part A	a) Rhône-Mérieux b) FR	a) Piglets b) Passive immunisation against neonatal colibacillosis	a) Suspension for injection b) 2ml c) 5	a) 02.10.96 b) 10.12.97 c) 191 days d) 245 days	a) 09.01.98 b) 14.04.98 c) 15.04.98 d) OJ No. C126 of 24.04.98
a) Nobilis IB4-91 b) Live vaccine c) Part B	a) Intervet International b) NL	a) Poultry, chicken b) Live vaccine against infectious bronchitis	a) Solution b) 30ml/1000 doses c) 5	a) 16.10.96 b) 12.11.97 c) 210 days d) 184 days	a) 12.12.97 b) 09.06.98 (corrigendum 05.08.98) c) 10.06.98 d) OJ No. C200 of 26.06.98
a) Suvaxyn Aujeszky 783+ O/W b) Live vaccine c) Part A	a) Solvay Duphar b) NL	a) Pigs b) Vaccine against Aujeszky disease	a) Solution for injection b) 2ml c) 3	a) 19.10.96 b) 08.04.98 c) 208 days d) 328 days	a) 08.05.98 b) 07.08.98 c) 10.08.98 d) OJ No. C269 of 28.08.98

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EMEA-FEDESA JOINT INFO-DAY ON VETERINARY BIOLOGICALS – THE EUROPEAN SCENE

The fifth in a series of joint EMEA-FEDESA Info-days was held today at the EMEA in London on the subject of veterinary biologicals in Europe following the December meeting of the Committee of Veterinary Medicinal Products. Previous Info-days have addressed wide ranging subjects including recommendations on optimising success in the centralised system, updates on progressing the establishment of old MRLs, current developments in the VICH initiative and briefings on guidelines under development at CVMP such as environmental safety and pharmocoviligance.

This latest meeting attracted over 60 delegates including representatives of the CVMP, Member States Competent Authorities, the European Commission, European Pharmacopoeia, Office International des Epizooties (OIE) and colleagues from companies throughout the European Union. This high attendance confirms the level of interest in the selected topic and continues the successful trends established in previous Info-days.

Opening the meeting Fernand Sauer, Executive Director of the EMEA focussed on the importance of the subjects being addressed, in particular the new information being presented on issues such as new trends in veterinary vaccines and biotechnology derived products as well as developments in community vaccination policy in the veterinary sector.
Mr Sauer also welcomed the opportunity provided by the meeting to industry representatives to review their experience of the centralised system in regard to biologicals.

The afternoon session included timely updates on harmonisation of testing of biologicals in the VICH process as well as on a global scale. Applicants were also reminded of their obligations under Community MRL legislation as it applies to vaccines and in addition of the need for compliance with pharmacopoeial monographs.

Under collaboration between the EMEA and the Commission significant progress was also announced on how to fulfil batch release testing requirements in the EU for centrally approved vaccines.

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