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

London, 10 September 1998
EMEA/CVMP/392/98

PRESS RELEASE

35th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

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

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	**9**	**9**	**10**
MRL procedures*	**38****	**20**	**5**

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

CENTRALISED PROCEDURES

2. The Committee adopted Opinions for two Type I Variations for products falling under Part A and B respectively of the Annex of Council Regulation (EEC) No. 2309/93

3. The Committee decided that the Applicants for the granting of Community marketing authorisations for two veterinary medicinal products intended for food-producing animals be invited to provide oral explanations before the Committee on outstanding issues before the Committee delivers its Opinions.

4. The Committee endorsed eligibility for three products, one falling under Part A and two falling under Part B of the Annex to Council Regulation (EEC) No. 2309/93, being new molecules for companion animals, and appointed Rapporteurs and Co-Rapporteurs for 2 products.

5. The Committee discussed the draft assessment report prepared by the Rapporteur and Co-Rapporteur for an application received by the Agency for a Community Marketing Authorisation for a Veterinary Medicinal Products falling under Part B of the Annex of Council Regulation No. (EEC) 2309/93. The Committee adopted a list of questions to be sent to the Applicant concerned.

6. The Committee considered the Follow-Up Measures as submitted by the Marketing Authorisation Holder for four products, one authorised under Part A and three authorised under Part B of the Annex to Council Regulation (EEC) No. 2309/93.

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ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

7. With respect to two substances already in Annex I of Council Regulation (EEC) No. 2377/90 the Committee recommended provisional MRLs for further target species and target tissues. The Committee adopted a status report and list of questions for one further new substance.

8. The Committee was unable to conclude on a recommendation for inclusion of another new substance into any of the annexes of Council Regulation (EEC) No. 2377/90, due to the inadequacy of the information submitted.

9. The Committee recommended the inclusion of one old substance into Annex I and seven old substances, one of vegetable origin, into Annex II of Council Regulation (EEC) No. 2377/90. One further substance was recommended for inclusion into Annexes I and III (according to target species), another was recommended to be included in Annexes II and III (according to target tissues).

   For a further substance, a recommendation was made to include it in Annex III to Council Regulation (EEC) No. 2377/90. The Committee also adopted two Opinions to extend the provisional MRLs for two old substances until the year 2001.

10. For a further four old substances, the Committee concluded that no recommendations for inclusion into any of the annexes of Council Regulation (EEC) No. 2377/90 could be made because of inadequacy of responses by the Applicants to the Committee's lists of questions.

11. The Committee recommended that, in future, a complete set of analytical methods in the appropriate format should be submitted to all parties concerned together with the response to the list of questions. This shall ensure that a complete, up-to-date set of analytical methods is available to the EMEA to accompany the Opinions recommending both Annex I and Annex III, which are subsequently transmitted to the European Commission.

GUIDELINES, POSITION PAPERS AND SOPs

The following documents were adopted for release for consultation:

12. Draft guidance paper on the acceptability of trade names for veterinary medicinal products processed through the centralised procedure (EMEA/CVMP/328/98).

The following documents were adopted following the close of the consultation period:

13. CVMP Position Paper on the Accelerated Evaluation of Products Indicated for Serious Diseases (EMEA/CVMP/092/98 - FINAL).

14. Revised Position Paper on batch potency testing of immunological veterinary medicinal products (CVMP/IWP/038/97-FINAL)

15. Revised Position Paper on indications and specific claims for veterinary vaccines (CVMP/IWP/042/97-FINAL)

INTERNATIONAL HARMONISATION

16. The Committee endorsed the recommendations to the VICH Steering Committee from the VICH Quality Expert Working Group concerning Stability Testing for New Veterinary Medicated Premixes and the recommendations concerning Inpurities in New Active Substances, Impurities in New Veterinary Medicinal Products and Residual Solvents.

17. The Committee also discussed the draft Guidelines on the Efficacy of Anthelmintics and endorsed their transmission to the VICH Steering Committee.

ANY OTHER BUSINESS

18. The next meeting of the Committee will be held on 13 - 15 October 1998.

Peter G.H. Jones
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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: September 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	a) 10.10.97 b) 16.01.98 c) OJ No. L 11 of

		d) 0	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	b) 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

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

(Status: September 1998)

TOTAL 423			
Annex I	Annex II	Annex III	Annex IV
52	322	38	11
Published in the Official Journal of the European Communities: 295			

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

(Status: September 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