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

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EMEA/CVMP/1222/02

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 10 to 12 December 2002

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Advocate**, ***an endectoparasiticide product*** from Bayer intended to treat mixed parasitic infections in dogs and cats. The application procedure was initiated on 19 December 2001 and the opinion was adopted on 11 December 2002 with an active review time of 210 days.

For further details please see the Summary opinion available on the EMEA web site: http://www.emea.eu.int

The Committee adopted by consensus a positive opinion on an extension application to the marketing authorisation for **Ibaflin Gel, *an antibacterial quinolone*** from Intervet intended to treat mixed dermal infections in dogs and cats. The application procedure was initiated on 8 August 2001 and the opinion was adopted on 11 December 2002 with an active review time of 210 days.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of **flugestone acetate** in Annex I of Council Regulation (EEC) No 2377/90 for ***caprine milk***. The MRL application for **flugestone acetate** was assessed under the procedure for "old substances" and the recommendation follows the assessment of the response to the list of questions further to the establishment of provisional MRLs for the substance for ***caprine milk*** (expiry date: 1 January 2003).

The Committee considered an appeal in respect to the MRL opinion for **oxolinic acid** following the assessment of the response to the list of questions further to the establishment of provisional MRL for this substance. Having received the grounds for appeal, the Committee revised the previous negative opinion and recommended the inclusion of **oxolinic acid** in Annex I of Council Regulation (EEC) No 2377/90 for pigs, chicken and fish.

For further details please see the Summary opinions available on the EMEA web site: http://www.emea.eu.int

The Committee considered a request from a Member State addressed to the European Commission to extrapolate the existing maximum residue limits for streptomycin and tetracycline to honey. The Committee concluded that such extrapolation was not possible and specific residue data in honey would be required in order to establish maximum residue limits for the abovementioned substances.

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Community Referrals

Referral under Article 20 of Directive 81/851/EEC (now Article 35 of Directive 2001/82/EEC)

The Committee heard the oral explanations of some of the companies involved in the appeal procedure against the opinion regarding long acting injectable veterinary medicinal products containing **benzathine benzylpenicillin**, adopted by the Committee during the October 2002 meeting. The decision on the appeal procedure is foreseen for the January 2003 meeting.

Guidelines, SOPs and Position Papers

The Committee adopted the following guidelines prepared by the Efficacy Working Party, further to the consideration of the comments received during the consultation period:

- Guideline on the **SPC for antimicrobial products** (EMEA/CVMP/612/01-FINAL)
- Guideline for the **Demonstration of efficacy for veterinary medicinal products containing antimicrobial substances** (EMEA/CVMP/627/01-FINAL)

The guidelines will come into effect on 11 June 2003.

The documents are available on the EMEA web site: http://www.emea.eu.int

The Committee adopted a guideline on **Standard Statements for the SPC of certain classes/types of veterinary medicinal product** (EMEA/CVMP/1166/02-CONSULTATION) prepared by the Efficacy Working Party for release for a 6-month period consultation.

The document is available on the EMEA web site: http://www.emea.eu.int

The Committee adopted a Revised Note for Guidance on **Summary of Active Substance Requirements in the Quality Part of the Dossier** (EMEA/CVMP/1069/02-CONSULTATION), prepared by the Quality Working Party for release for a 6-month period of consultation. The publication of the document on the EMEA web site: *http://www.emea.eu.int* will follow the adoption by the CPMP at the December 2002 meeting (17-19 December 2002).

The Committee adopted a Position Paper on the **Maximum In-Use Shelf-Life for Medicated Drinking Water** (EMEA/CVMP/1090/02-FINAL), prepared by the Quality Working Party.

The document is available on the EMEA web site: http://www.emea.eu.int

Pharmacovigilance

The Committee agreed the proposals to promote and improve pharmacovigilance reporting and to strengthen the EU pharmacovigilance system for veterinary medicinal products (EMEA/CVMP/656/02-FINAL) based on the recommendations of the Joint EMEA/FEDESA/FVE Workshop on the EU Pharmacovigilance system meeting in Madrid, Spain, on 27-28 May 2002 further to the endorsement of the measures proposed by the Heads of European Veterinary Regulatory Authorities (HEVRA) during the meeting held in Denmark in November 2002.

The document is available on the EMEA web site: http://www.emea.eu.int

Post-authorisation surveillance

The Committee endorsed the list of veterinary medicines centrally authorised selected for sampling and testing procedure in 2004. They include Eurican Herpes 205, Pirsue, Virbagen Omega, Zubrin, Pulsaflox, Doxirobe gel and Econor.

Organisational issues

Further to the resignation of Steve Dean as Chairman of the Committee for Veterinary Medicinal Products due to new professional responsibilities, the Committee elected the previous Vice-Chairman Gérard Moulin as the new Chairman for the remaining year of the current 3-year term of the Committee. Hans Hoogland was elected as Vice-Chairman of the Committee.

The Committee expressed its gratitude and appreciation to Steve Dean for his outstanding service to the Committee as Chairman for the past 2 years.

The next meeting of the CVMP will be held on 14-16 January 2003

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This press release and other documents are available on the Internet at the following address:
http://www.emea.eu.int

Annex I to CVMP Press Release December 2002

Marketing Authorisations

	1995-2001	2002	Overall Total
Applications submitted	47	3	50
Withdrawals	7	1	8
Positive CVMP opinions	30	8	38
Negative CVMP opinions[1]	0	0	0

Variations

	1995-2001	2002	Overall Total
Variations type I	84	14	98
Variations type II	25	12	37

Extensions

	1995-2001	2002	Overall Total
Extensions (Annex II applications) submitted	26	7	33
Withdrawals	0	1	1
Positive opinions	11	4	15
Negative opinions	0	0	0

[1] In case of appeal the opinion will not be counted twice

Renewals of marketing authorisations

	1995-2001	2002	Overall Total
Renewal applications submitted	2	5	7
Renewal positive opinions	2	3	5
Renewal negative opinions	0	0	0

Scientific advice

	1995-2001	2002	Overall Total
Applications submitted	16	4	20

Establishment of maximum residue limits

	1995-2001			2002			Overall Total
	Full	Extension/ Modification	Total	Full	Extension/ Modification	Total	
Applications submitted	47	66	113	3	7	10	123
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	31	73	114	5	6	11	125
Negative opinions**	5	5	10	0	0	0	10

*Including 15 opinions recommending definitive MRLs for substances with previously provisional maximum residue limits

**Including 2 opinions (1 full, 1 extension) concluding that final maximum residue limits could not be established for substances with provisional maximum residue limits previously established

Referrals

	1995-2001	2002	Overall Total
Referrals	5	3	8