European Medicines Agency
Veterinary Medicines and Inspections

London, 15 November 2004
EMEA/CVMP/1076/04-corr[1]

PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 9 to 11 November 2004

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted positive opinions by consensus on initial marketing authorisation applications for Purevax RCPCh FeLV, Purevax RCPCh, Purevax RCP FeLV, Purevax RCP, Purevax RC and Purevax RCCh, from Merial. The vaccine having most valencies, Purevax RCPCh FeLV is an associated vaccine containing live and inactivated components including: a modified live feline herpesvirus (F2 strain), a combination of two inactivated purified caliciviruses (FCV431 and FCVG1 strains), a modified live *Chlamydophila felis* (strain 905), a modified live infectious panleucopenia virus (strain PLI IV) and a recombinant canarypox-FeLV (strain vCP97) against feline leukaemia. All 5 other products of the Purevax range are lesser valent combinations of the above. The application procedure for Purevax RCPCh FeLV was initiated on 15 October 2003 and the opinion was adopted on 10 November 2004 with an active review time of 203 days. All other products of the range were initiated at various later dates but had the same Opinion date of 10 November 2004 and the same active review time of 203 days.

The Committee adopted a positive opinion by consensus on an extension marketing authorisation application for Metacam 20mg/ml solution for injection for horses (meloxicam), from Boehringer Ingelheim Vetmedica indicated for use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders. The application procedure was initiated on 6 May 2004 and the opinion was adopted on 10 November 2004 with an active review time of 160 days.

For further details please see the Summary opinions which will be available on Monday 15 November 2004 on the EMEA web site: http://www.emea.eu.int

The Committee adopted a positive opinion by consensus for a Type II variation for Advocate regarding the addition of claims against ear mite infestations in cats and dogs, and against sarcoptic mange and demodicosis in dogs.

The Committee adopted a positive opinion by consensus for a Type II variation for ProteqFlu-Te regarding a change of the manufacturing site of the Tetanus active ingredient.

[1] Correction introduced in Annex I (page 4) with regard to figures on CVMP opinions on marketing authorisations and extensions

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

Maximum Residue Limits

The Committee adopted a positive opinion by consensus recommending the inclusion of carprofen in Annex II of Council Regulation (EEC) No. 2377/90 with regard to bovine milk. The substance is currently included in Annex I of Council Regulation (EEC) 2377/90 for bovine and porcine tissues with the exemption of use in animals (cows) producing milk for human consumption. As a consequence of this recommendation the Committee recommended the modification of the current Annex I entry removing the exemption of use in animals producing milk for human consumption. The application procedure was initiated on 13 August 2004 and an opinion recommending the inclusion of carprofen in Annex II for bovine milk and the modification of the current Annex I was adopted on 10 November 2004 with an active review time of 90 days.

The Committee adopted by majority a positive opinion recommending the modification of the ADI for ivermectin as well as the MRLs currently established for bovine, porcine, ovine, *Equidae*, and deer (including reindeer). The MRLs now recommended for all mammalian food producing species are harmonised for fat, liver and kidney. The application procedure was initiated on 7 April 2003 and the opinion mentioned above was adopted on 10 November 2004 with an active review time of 118 days.

For further details please see the Summary opinions which will be available on Monday 15 November 2004 on the EMEA web site: http://www.emea.eu.int

Guidelines, SOPs and Position Papers

The CVMP considered comments received from Interested Parties during the consultation period of the Draft "Guideline on Standard Statements for the SPC of certain classes/types of veterinary medicinal products" (EMEA/CVMP/1166/02) and concluded that the development of such a guideline would be discontinued.

International harmonisation

The Committee adopted the VICH guideline GL38 on Environmental Impact Assessments for veterinary medicinal products - Phase II, following consideration of the comments received during the public consultation (CVMP/VICH/790/03-FINAL) for implementation within 12 months.

The Committee adopted the VICH guideline GL 41 on Target Animal Safety: Examination of live veterinary vaccines in target animals for absence of reversion to virulence for release for a 6-month period of consultation (CVMP/VICH/1052/04-CONSULTATION).

The documents will be available on the EMEA web site: http://www.emea.eu.int on Monday 15 November 2004

Organisational issues

The Committee appointed four new co-opted members to join the Committee as from December 2004. The four co-opted members and the experience for which they have been appointed are:

- Ivo Claassen – quality aspects of biotechnology products
- Peter Ekström – clinical medicine in large animals
- Rory Breathnach – clinical medicine in companion animals
- Christian Friis - safety and risk assessment

The possibility of co-opting additional members (maximum five) is provided in the new legislation that came into force in May 2004.

As no nominations have yet been received, the Committee will further consider the appointment of a fifth member of the Committee to complement the expertise on clinical medicine of intensive production, with the aim to appoint this member within the next 3 months.

The Committee discussed the preparation of the Informal CVMP meeting to be held in Rotterdam, The Netherlands on 1-2 December 2004 at the initiative of the Dutch Authorities under the activities of the Presidency of the European Union. The Committee agreed that the meeting would consider the following items:

- alternatives to animal testing;
- outcome and follow-up of the audit of the Committee held on 11-15 October 2004;
- how to improve the working practices of the Committee focusing on the procedure for appointment of rapporteurs, the roles and duties of working party's members and how to improve communication on CVMP decisions to the public;
- development of scientific memory databases.

The CVMP adopted the revised mandates of all Working Parties on the basis of a new template developed with the aim to harmonise the presentation, provide clearer information on the objectives and define the rules of procedure with the working parties and their relation with the CVMP.

The next meeting of the CVMP will be held on 7-9 December 2004

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

Marketing Authorisations

	1995-2003	2004	Overall Total
Applications submitted	60	7	67
Withdrawals	9	1	10
Positive CVMP opinions	42	10	52
Negative CVMP opinions[2]	0	0	0

Variations

	1995-2003	2004	Overall Total
Variations type I	146	16	162
Variations type II	49	9	58
Transfers	4	1	5

Extensions

	1995-2003	2004	Overall Total
Extensions (Annex II applications) submitted	35	5	40
Withdrawals	1	0	1
Positive opinions	21	2	23
Negative opinions	0	0	0

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

Renewals of marketing authorisations

	1995-2003	2004	Overall Total
Renewal applications submitted	11	3	14
Renewal positive opinions	9	5	14
Renewal negative opinions	0	0	0

Scientific advice

	1995-2003	2004	Overall Total
Applications submitted	22	4	26

Establishment of maximum residue limits

	1995-2003			2004			Overall Total
	Full	**Extension/ Modification**	**Total**	**Full**	**Extension/ Modification**	**Total**	
Applications submitted	52	81	133	4	7	11	144
Withdrawals	5	4	9	0	0	0	9
Positive opinions[*]	37	86	123	8	7	15	136
Negative opinions[**]	5	5	10	1	0	1	11

[*] Including 16 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

	1995-2003	2004	Overall Total
Referrals	8	2	10