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

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EMEA/CVMP/081/04

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 13 to 15 January 2004

G. Moulin and J. P. Hoogland were re-appointed as Chairman and Vice-Chairman of the Committee. The Committee also confirmed the current chairpersons of the Working Parties.

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted positive opinions by consensus for type II variations:

- for **Dexdomitor** regarding the addition of an indication for deep sedation and analgesia in dogs in concomitant use with butorphanol for medical and minor surgical procedures;
- for **Stronghold** regarding the addition of an indication for the treatment of ear mites in dogs.

Maximum Residue Limits

The Committee adopted by consensus positive opinions:

- recommending the inclusion of **diclazuril** in Annex II of Council Regulation (EEC) No. 2377/90 for **all ruminants** and **porcine** species. The application procedure was initiated on 17 October 2003 with an active review time of 90 days.
- recommending the inclusion of **tulathromycin** in Annex I of Council Regulation (EEC) No. 2377/90 for **bovine** and **porcine** species further to establishment of provisional MRLs.

The Committee also concluded the assessment of an application for the establishment of maximum residue limits for **roxarsone** in **chicken**. However, no recommendation for the inclusion in any of the annexes of Council Regulation (EEC) No. 2377/90 was possible and a negative opinion was adopted. The application procedure was initiated on 21 August 2002 with an active review time of 115 days. An appeal against this opinion may be launched by the applicant within the deadlines provided by legislation.

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

Scientific advice

The Committee agreed scientific advice regarding specific efficacy requirements for a feline vaccine, where the addition of a recombinant canarypox-rabies component is added to an existing product containing a number of different antigens.

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Renewals of Marketing Authorisations

The Committee adopted a positive opinion by consensus for the renewal of the marketing authorisation for **Econor**. The Committee concluded that the quality, safety and efficacy of the product continued to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation.

International Harmonisation

The Committee adopted the VICH guideline GL 27 on Pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to **Antimicrobial resistance** (CVMP/VICH/644/01-FINAL).

The guideline will enter into force on 15 December 2004 and will supersede the CVMP guideline on pre-authorisation studies to assess the potential for Resistance resulting from the use of Antimicrobial Veterinary Medicinal Products (EMEA/CVMP/244/01-FINAL). The guideline defines the pre-authorisation requirements for veterinary medicinal products for food producing animals with respect to antimicrobial resistance of the European Union, Japan and USA. A CVMP explanatory note, at the beginning of the guideline, specifies the scope of the guideline in the context of the European Union regulatory framework.

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

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Nobivac Bb** and **Halocur** and concluded that no actions or changes to the product literature of the products were required.

Safety

The Committee adopted for release for a 6-month period of consultation a guideline on injection site residues, prepared by the Safety Working Party (EMEA/CVMP/542/03-CONSULTATION). This guideline is a revision of the Working Document prepared by the Safety of Residues Working Party and agreed by the CVMP in 1994 on principles concerning the assessment of injection site residues.

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

Immunologicals

The Committee adopted for release for a 6-month period of consultation a guideline on live recombinant vector vaccines for veterinary use, prepared by the Immunologicals Working Party, (EMEA/CVMP/004/04-CONSULTATION).

The Committee also adopted for release for a 2-month period of consultation a concept paper on the need to revise the Note for Guidance on Requirements For Combined Vaccines, prepared by the Immunologicals Working Party (EMEA/CVMP/018/04-CONSULTATION).

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

The next meeting of the CVMP will be held on 10-12 February 2004

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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	4	64
Withdrawals	9	1	10
Positive CVMP opinions	42	0	42
Negative CVMP opinions[1]	0	0	0

Variations

	1995-2003	2004	Overall Total
Variations type I	146	1	147
Variations type II	49	2	51
Transfers	4	1	5

Extensions

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

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

Renewals of marketing authorisations

	1995-2003	2004	Overall Total
Renewal applications submitted	11	0	11
Renewal positive opinions	9	1	10
Renewal negative opinions	0	0	0

Scientific advice

	1995-2003	2004	Overall Total
Applications submitted	22	0	22

Establishment of maximum residue limits

	1995-2003			2004			Overall Total
	Full	**Extension/ Modification**	**Total**	**Full**	**Extension/ Modification**	**Total**	
Applications submitted	52	81	133	0	0	0	133
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	37	86	123	2	0	2	125
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	0	8