



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

London, 14 May 2004  
EMEA/CVMP/477/04

**PRESS RELEASE**  
**COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE**  
**Meeting of 11 to 13 May 2004**

On the occasion of the enlargement of the EU, an information session for CVMP Members was held on 10-11 May 2004.

**CVMP Opinions on Veterinary Medicinal Products**

The Committee adopted a positive opinion by consensus on an initial marketing authorisation application for Nobivac Piro. This product contains soluble parasite antigen (SPA) from *Babesia canis* and *Babesia rossi* cultures from Intervet International BV and is intended for active immunisation of dogs of 6 months of age or older against *Babesia canis* to reduce the severity of clinical signs associated with acute Babesiosis (*B. canis*) and anaemia as measured by Packed Cell Volume (PCV). The application procedure was initiated on 17 September 2003 and the opinion was adopted on 12 May 2004 with an active review time of 210 days.

The Committee adopted a positive opinion by majority on an initial marketing authorisation application for Aivlosin, containing acetylisovaleryltylosin as active ingredient, from ECO Animal Health intended for treatment and prevention of Swine Enzootic Pneumonia caused by susceptible strains of *Mycoplasma hyopneumoniae* in pigs. The application procedure was initiated on 13 August 2003 and the opinion was adopted on 12 May 2004 with an active review time of 210 days.

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

**Maximum Residue Limits**

The Committee adopted an opinion by consensus recommending the extension of the current Annex II entry for cloprostenol and R-cloprostenol in cattle, pigs and *Equidae* to goats further to a request from a company.

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

## Scientific advice

The Committee agreed scientific advice regarding the clinical development of an oncology product for mast cell tumours in dogs. This advice was the first joint collaboration in relation to scientific advice under the veterinary confidentiality agreement between EMEA and US FDA and was initiated at the request of the applicant.

The Committee also agreed scientific advice regarding the clinical development of a veterinary product for treatment of hyperphosphataemia associated with chronic renal failure in cats.

## Availability

The Committee adopted the criteria for granting free scientific advice for veterinary medicinal products for Minor Uses and Minor Species Products (EMEA/CVMP/1136/03-Final) following public consultation. This free scientific advice is intended as an incentive to industry to develop veterinary medicinal products for therapeutic indications where there is currently a gap of authorised medicines. With the support of the EMEA Management Board a Community funded budget has been made available for a 1-year pilot project. The pilot phase will come into effect on 14 May 2004.

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

## Pharmacovigilance

The Committee reviewed a Periodic Safety Update Report (PSUR) for **Stronghold** and concluded that no further action or changes to the product literature of the product were required.

## Guidelines, SOPs and Position Papers

The Committee adopted a revised guideline on the processing of Renewals in the Centralised Procedure; the update takes into account experience gained over the last few years and includes practical guidance to Marketing Authorisation Holders with regard to the submission of product literature and clarification with regard to the timing of Periodic Safety Update Reports (PSURs). The guideline will be forwarded to the European Commission's Notice to Applicants Working Group.

The Committee adopted for release a document prepared by the Joint CPMP/CVMP Quality Working Party seeking comments from industry on the application of the future harmonised Ph.Eur. text "Uniformity of Dosage Units" to new and existing marketing authorisations (EMEA/CVMP/483/04). The deadline for comments is 30 July 2004.

The Committee also adopted the following new guideline prepared by the Joint CPMP/CVMP Quality Working Party, following the close of its consultation period: Guideline on the Chemistry of New Active Substances (EMEA/CVMP/541/03). The implementation date is 1 December 2004.

*These documents are available on the EMEA web site: <http://www.emea.eu.int>*

The Committee adopted a new guideline annex prepared by the Joint CPMP/CVMP Quality Working Party. This guidance document (EMEA/CVMP/489/04) will form Annex II (Non-standard processes) to the Joint CPMP/CVMP Guideline on Process Validation. Publication on the EMEA web site <http://www.emea.eu.int> of this new annex to the joint guideline will follow its final adoption by the CPMP, which is foreseen for their next meeting, 1-3 June 2004.

The Committee adopted a revision of the VICH guideline 28 "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing (CVMP/VICH/645/01-FINAL)" with an amendment on the tissues to be examined, for release for a 2-month period of consultation.

*The document will be published in the course of next week on the  
EMEA web site: <http://www.emea.eu.int>*

### **Organisational issues**

The Committee agreed the agenda of the Informal CVMP to be held in Cork, Ireland, on 24-25 May 2004 which will focus on discussion of the following points: Preparation of Quality Audit of CVMP in October 2004 and the EMEA Roadmap to 2010, enlargement of the EU – impact on CVMP organisation, and quality of CVMP Assessment Reports.

The Committee agreed the Programme for the Info day with Interested Parties to be held on 17 June 2004 at the EMEA which will focus on The European Medicines Agency Roadmap to 2010. On 18 June 2004 the EMEA and CVMP Safety experts will hold a Focus Group with industry to discuss Injection site residues.

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

The next meeting of the CVMP will be held on 15-17 June 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>

**Annex I to CVMP Press Release May 2004**

Marketing Authorisations

	1995-2003	2004	Overall Total
<b>Applications submitted</b>	60	6	66
<b>Withdrawals</b>	9	1	10
<b>Positive CVMP opinions</b>	42	3	45
<b>Negative CVMP opinions<sup>1</sup></b>	0	0	0

Variations

	1995-2003	2004	Overall Total
<b>Variations type I</b>	146	4	150
<b>Variations type II</b>	49	4	53
<b>Transfers</b>	4	1	5

Extensions

	1995-2003	2004	Overall Total
<b>Extensions (Annex II applications) submitted</b>	35	4	39
<b>Withdrawals</b>	1	0	1
<b>Positive opinions</b>	21	1	22
<b>Negative opinions</b>	0	0	0

<sup>1</sup> In case of appeal the opinion will not be counted twice

Renewals of marketing authorisations

	1995-2003	2004	Overall Total
<b>Renewal applications submitted</b>	11	0	11
<b>Renewal positive opinions</b>	9	2	11
<b>Renewal negative opinions</b>	0	0	0

Scientific advice

	1995-2003	2004	Overall Total
<b>Applications submitted</b>	22	3	25

Establishment of maximum residue limits

	1995-2003			2004			Overall Total
	Full	Extension/Modification	Total	Full	Extension/Modification	Total	
<b>Applications submitted</b>	52	81	133	2	3	5	138
<b>Withdrawals</b>	5	4	9	0	0	0	9
<b>Positive opinions*</b>	37	86	123	4	2	6	129
<b>Negative opinions**</b>	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
<b>Referrals</b>	8	1	9