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

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EMEA/CVMP/409/04

PRESS RELEASE

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 14 to 15 April 2004

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for an extension application for Virbagen Omega from Virbac S.A. Virbagen Omega contains recombinant omega interferon and is now also indicated for the treatment of cats infected with FeLV and/or FIV, in non-terminal clinical stages, from the age of 9 weeks (the initial authorisation was for dogs). The procedure was initiated on 26 March 2003 and the opinion was adopted on 14 April 2004 with an active review time of 210 days.

The Committee adopted by consensus a positive opinion for a Type II variation for Porcilis Porcoli regarding the introduction of an additional primary packing type (PET vials).

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of sorbitan sesquioleate in Annex II of Council Regulation (EEC) No. 2377/90 for all food producing species further to a request from a company and considering that sorbitan sesquiolate would be covered by the assessment and existing Annex II entries for closely related sorbitan esters.

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 in relation to quality, safety and clinical development regarding a West Nile Virus vaccine for horses.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for Nobilis OR inac, Metacam and Sevoflo and concluded that no further action or changes to the product literature of the products were required.

The Committee adopted a list of species and breeds (EMEA/CVMP/553/03-FINAL), following the close of its consultation period. This list details the terminology agreed for use with electronic reporting of adverse reactions in veterinary pharmacovigilance to indicate animal species and breeds.

The Committee adopted a guideline on harmonising the approach to causality assessment for suspected adverse reactions to veterinary medicinal products (EMEA/CVMP/552/03-FINAL) having considered comments received during its consultation. This document gives detailed advice on factors to consider when assessing the causal relationship between a veterinary medicinal product and a suspected adverse reaction.

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The Committee adopted a revision of the guideline on procedures for competent authorities for pharmacovigilance of veterinary medicines (EMEA/CVMP/345-98-FINAL-Rev.1). The changes mainly relate to provisions for future electronic reporting by Member States' competent authorities. Due to the nature of the changes no consultation was considered necessary.

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

Quality issues

The Committee adopted for release, for a 6-month period of consultation, a guideline prepared by the Joint CPMP/CVMP Quality Working Party on stability testing for applications for variations to a marketing authorisation (EMEA/CVMP/373/04-Consultation).

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

Safety issues

The Committee adopted for release, for a 6-month period of consultation, a guideline prepared by the Safety Working Party on user safety for pharmaceuticals (EMEA/CVMP/543/03-Consultation). A similar guideline on user safety for immunologocal veterinary medicinal products will be developed in the future.

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

Efficacy issues

The Committee adopted for release, for a 2-month period of consultation, a concept paper prepared by the Efficacy and Safety Working Parties on the revision of the guideline for fixed combination Products (EMEA/CVMP/384/04).

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

Organisational issues

The Committee discussed organisational and procedural issues in preparation for the establishment of a new Committee as well as new advisory groups from May 2004. This was in consideration of the European Union enlargement and the implementation of the new EU legislation on pharmaceuticals in order to ensure a smooth transition.

The next meeting of the CVMP will be held on 11-13 May 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	5	65
Withdrawals	9	1	10
Positive CVMP opinions	42	1	43
Negative CVMP opinions[1]	0	0	0

Variations

	1995-2003	2004	Overall Total
Variations type I	146	4	150
Variations type II	49	3	52
Transfers	4	1	5

Extensions

	1995-2003	2004	Overall Total
Extensions (Annex II applications) submitted	35	1	36
Withdrawals	1	0	1
Positive opinions	21	1	22
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	2	11
Renewal negative opinions	0	0	0

Scientific advice

	1995-2003	2004	Overall Total
Applications submitted	22	3	25

Establishment of maximum residue limits

	1995-2003			2004			Overall Total
	Full	**Extension/ Modification**	**Total**	**Full**	**Extension/ Modification**	**Total**	
Applications submitted	52	81	133	2	3	5	138
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	37	86	123	4	1	5	128
Negative opinions**	5	5	10	1	0	1	11

*Including 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	1	9