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

London, 4 October 2002
EMEA/CVMP/969/02

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 1 to 3 October 2002

CVMP Opinions on Medicinal Products

The Committee adopted by majority a positive opinion on an initial marketing authorisation application for **Nobilis OR inac**, an ***inactivated bacterial vaccine*** from Intervet. The product is intended to provide passive immunity against *Ornithobacterium rhinotracheale* in broiler breeders. The review of the application was initiated on 19 January 2000 and the opinion adopted on 2 October 2002 with an active review time of 206 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 for a type II variation regarding compliance with transmissible animal spongiform encephalopathy (TSE) requirements for **Porcilis Pesti**.

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Quadrisol (*Vedaprofen*)**. The Committee concluded that the quality, safety and efficacy of the product continues to be adequately and sufficiently demonstrated and therefore recommended the renewal of the marketing authorisation.

Scientific Advice

The Committee agreed scientific advice regarding the extent of purity testing of live vaccines for which no European Pharmacopoeia Monograph exists. Specific questions concerning requirements for sterility of live bacterial vaccines, purity testing requirements and use of other non-pharmacopoeial methods were addressed.

Maximum Residue Limits

The Committee noted the notification of an appeal against the negative opinion for **oxolinic acid** adopted by the Committee during the September 2002 meeting. The decision on the appeal procedure is foreseen for the December 2002 meeting.

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

Community Referrals

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

The Committee concluded the evaluation of the referral initiated by Ireland under Article 20 of Directive 81/851/EEC regarding long acting injectable veterinary medicinal products containing **benzathine benzylpenicillin**, authorised nationally. The review was initiated due to safety concerns regarding residues remaining at the injection site above the MRLs at the end of the withdrawal period.

The Committee adopted by majority an opinion recommending the suspension of all marketing authorisations for injectable veterinary medicinal products containing benzathine benzylpenicillin, which are intended for administration to food producing species. The reasons being the following:

- it was not possible based on the data made available to the Committee to establish a withdrawal period;
- the currently authorised withdrawal periods are inadequate to ensure that residues at the injection site do not exceed the MRL;
- the currently authorised withdrawal periods are inadequate to ensure that foodstuffs obtained from treated animals do not contain residues which might constitute a health hazard to the consumer throughout the Community.

The Committee will review the opinion for suspension within one year or as soon as new data is submitted to the Committee for evaluation.

An appeal against this opinion may be launched by the companies concerned within the deadlines provided by legislation.

Referral under Article 33 of Directive 2001/82/EC

The Committee considered the notification for a referral for arbitration under Article 33 of Directive 2001/82/EC for **Orbax** (**Orbifloxacin**) from Spain and Denmark. The referral concerns a mutual recognition procedure for a "line extension" initiated due to concerns on the risk benefit of the higher dose proposed. A Rapporteur and a Co-Rapporteur were appointed and the review procedure is now underway.

Guidelines, SOPs and Position Papers

The Committee released a position paper for 6 months' consultation **on requirements for vaccines against foot and mouth disease** (EMEA/CVMP/775/02-CONSULTATION) developed by the ad hoc group of the Immunologicals Working Party on foot and mouth disease vaccines for release for a 6-month period of consultation. This is as a consequence of the current lack of authorised vaccines for the use in emergency situations for the control of foot and mouth disease in the European Union. The objective of this position paper is to clarify the requirements that must be met for foot and mouth disease vaccines to be released as authorised products.

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

The Committee adopted a **Position paper on the re-establishment of working seeds and working cell banks using TSE compliant materials** prepared by the CPMP Biotech Working Party. The publication of the document on the EMEA web site (http://www.emea.eu.int) will follow the adoption by the CPMP at the October meeting (15-17 October 2002).

Pharmacovigilance issues

The Committee reviewed Periodic Safety Update Reports (PSURs) on **Virbagen Omega** and **Ibaflin** and concluded that the information available did not create a need for further action or changes to the Summary of Product Characteristics (SPC) of the products.

The Committee considered proposals from the Pharmacovigilance Workshop held in Spain, in May 2002, jointly by EMEA, European Federation of Animal Health (FEDESA) and the European Federation of Veterinarians (FVE) as how to promote and optimise pharmacovigilance reporting in the EU. The Committee will now finalise a set of proposals for further discussion with Heads of European Veterinary Regulatory Authorities for medicinal products (HEVRA) and for further reporting to the Management Board of the Agency towards the end of the year.

International Harmonisation

The Committee reviewed the following VICH guidelines:

- VICH GL33: Safety of Veterinary Drugs in Human Food: **General approach to testing**
- VICH GL31: Safety of Veterinary Drugs in Human Food: **Repeat-Dose (90 days) Toxicity Testing**
- VICH GL32: Safety of Veterinary Drugs in Human Food: **Developmental Toxicity Testing**

following the consultation period.

These guidelines are intended to be finalised by the VICH Expert Working Group at their next meeting to be held in Tokyo on 8-9 October 2003.

The Committee also commented on the draft VICH guidelines currently under preparation on:

- Safety of Veterinary Drugs in Human Food: **Repeat Dose (Chronic Toxicity) Testing**

The Committee agreed comments on maximum residue limits proposed by Codex Alimentarius for ivermectin, oxytetracyclin, cefuroxime, cypermethrin, alphacypermethrin, dihydrostreptomycin/streptomycin, lincomycin and melengestrol acetate, further to the request of the European Commission and in preparation of the EU position at the next Codex Alimentarius (CCRDVF) meeting to be held in Washington in March 2003.

Organisational Issues

The Committee adopted the work plans for 2003-2004 for the CVMP working parties (Pharmacovigilance, Efficacy, Safety and Immunologicals Working Party) as well as for the CVMP ad hoc group on Environmental Risk Assessment. The work plans will be incorporated on the EMEA Work programme to be published later this year.

The document (EMEA/CVMP/829/02) is available on the EMEA Web site http://www.emea.eu.int

The next meeting of the CVMP will be held on 12-14 November 2002

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

	1995-2001	2002	Overall Total
Applications submitted	47	0	47
Withdrawals	7	1	8
Positive CVMP opinions	30	4	34
Negative CVMP opinions[1]	0	0	0

Extensions

	1995-2001	2002	Overall Total
Extensions (Annex II applications) submitted	26	3	29
Withdrawals	0	1	1
Positive opinions	11	2	13
Negative opinions	0	0	0

Renewals of marketing authorisations

	1995-2001	2002	Overall Total
Renewal application submitted	2	3	5
Renewal positive opinions	2	1	3
Renewal negative opinions	0	0	0

Scientific advice

	1995-2001	2002	Overall Total
Applications submitted	17	4	21

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

Establishment of maximum residue limits

	1995-2001			2002			Overall Total
	Full	**Extension/ Modification**	**Total**	**Full**	**Extension/ Modification**	**Total**	
Applications submitted	47	66	113	2	6	8	121
Withdrawals	5	4	9	0	0	0	9
Positive opinions	31	73	114	5	5	10	124*
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 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