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

London, 13 February 2004
EMEA/CVMP/213/04

PRESS RELEASE

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 10 to 12 February 2004

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for Equilis StrepE from Intervet International BV intended for the immunisation of horses against *Streptococcus equi*. The application procedure was initiated on 13 November 2002 and the opinion was adopted on 10 February 2004 with an active review time of 210 days.

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

The Committee adopted a positive opinion by consensus for a Type II variation for **Porcilis AR-T DF** regarding a quality issue.

Maximum Residue Limits

The Committee adopted by consensus an opinion recommending the extension of the current Annex II entry of Council Regulation (EEC) No. 2377/90 for **sodium salicylate** to oral use in bovine and porcine species. The application procedure was initiated on 14 November 2003 with an active review time of 90 days

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

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Locatim**. 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.

Community Referrals

The Committee concluded the evaluation of the referral initiated by Germany under Article 34 of Council Directive 2001/82/EC regarding the nationally authorised product Eprinex Pour-on. The referral had been initiated in order to harmonise the different withdrawal periods established by Member States for the product and CVMP adopted by consensus an opinion recommending 15 days as the withdrawal period for meat. The zero days withdrawal period for milk established in the different Member States remains unchained.

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

The Committee considered the notification for a referral from United Kingdom under Article 34 of Council Directive 2001/82 for Dectomax 1% injectable solution for cattle and sheep. The referral concerns a product authorised nationally in 15 Member States, Norway and Iceland and was initiated due to divergent decisions take by Members States with regard to the withdrawal period for the product with regard to sheep meat. A Rapporteur and a Co-Rapporteur were appointed and the review procedure is now underway. A list of questions to be sent to the Marketing Authorisation Holders was agreed.

Antimicrobial Resistance

The Committee considered the report of the Joint FAO/WHO/OIE first Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance held in Geneva, Switzerland in December 2003 and the recommendations from the meeting to be discussed at the second Workshop on the subject to be held in Oslo, Norway in March 2004 to which the EMEA/CVMP has been invited to send a representative. The Committee expressed its concerns at some of the recommendations and agreed a communiqué to be sent to FAO/WHO/OIE. This will be published on the EMEA Website.

Scientific advice

The Committee agreed to a request for a fee reduction for scientific advice for a vaccine in agreement with criteria agreed by the EMEA Management Board. This request precedes the provision of free scientific advice for minor uses and minor species for a 12-month pilot period, which is anticipated to come into effect in the next few months.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Eurifel RCP FeLV**, **Porcilis AR-T DF**, **Virbagen Omega**, **Doxirobe Gel**, and **Pruban** and concluded that no actions or changes to the product literature of the products were required.

The Committee adopted the revised EMEA Crisis Management Plan for centrally authorised veterinary medicinal products (EMEA/CVMP/159/04).

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

Quality

The Committee adopted the following guideline prepared by the Joint CPMP/CVMP Quality Working Party, following the close of its consultation period:

- Guideline on **active substance master file procedure** (EMEA/CVMP/134/02). This joint guideline was adopted at the January 2004 CPMP meeting. The implementation date is 1 September 2004.

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

The Committee also adopted for release for a 6-month period of consultation, a revised guideline:

- Guideline on **plastic primary packaging materials** (EMEA/CVMP/205/04). Publication of this joint guideline on the EMEA web site http://www.emea.eu.int will follow its final adoption by the CPMP at their February 2004 meeting (24-26 February 2004).

Availability

The Committee agreed and adopted the criteria for granting free scientific advice in respect of supporting the research and development of veterinary medicinal products destined for administration for minor use in major species and minor species. The document is being released for a 1-month period of consultation (EMEA/CVMP/1136/03 – CONSULTATION)

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

The Committee reviewed detail comments on the Availability of products for minor uses and minor species (MUMs) position paper after the end of the consultation period and will now move to consider and further revise the document.

Organisational issues

The Committee was informed of the launch of the pilot phase of the new EMEA policy on handling conflicts of interest. The new policy which introduces more transparent criteria for the assessment of conflicts of interest is undergoing a 3-month pilot phase involving members of the EMEA scientific committees and their working parties only and is expected to enter into force by April 2004.

Further to a request from IFAH-Europe the Committee agreed that CVMP Working Parties work programmes would be released and published on the EMEA website. The CVMP also agreed that each of the Working Parties would convene meetings with interested parties to discuss the work programmes

The next meeting of the CVMP will be held on 16-18 March 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	4	64
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	3	149
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	2	11
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	1	1	2	135
Withdrawals	5	4	9	0	0	0	9
Positive opinions[*]	37	86	123	2	1	3	126
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	1	9