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

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EMEA/CVMP/943/03/corrigendum

PRESS RELEASE

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 14 to 16 October 2003

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for an extension to the Marketing Authorisation for **Gallivac HVT IBD**, a vaccine for use in poultry, to include administration by the *in ovo* route.

The Committee adopted by consensus a positive opinion for two Type II variations for **Econor** adding two new indications for pigs in the same therapeutic area: "The treatment of clinical signs of porcine proliferative enteropathy (ileitis)" and "The prevention of porcine colonic spirochaetosis (colitis) when the disease has been diagnosed in the herd."

The Committee also adopted by consensus a positive opinion for a Type II variation for **Zubrin** allowing the administration of the product to dogs together with food. This variation also amended the current warnings in relation to undesirable effects as considered necessary from the evaluation of the Periodic Safety Update Report (PSUR) discussed at the September meeting of the Committee.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of **kanamycin** (all food producing species, except fish) in Annex I of Council Regulation (EEC) No 2377/90, further to establishment of provisional MRLs. The application was submitted under the procedure for the so-called "old substances" ("old" Article 7 of Council Regulation (EEC) No 2377/90) and the current provisional MRLs will expire on 1 January 2004.

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

International Harmonisation

The Committee adopted the draft VICH guideline GL 38 on Environmental Impact Assessments (EIAs) for Veterinary Medicinal Products (VMPs) – Phase II for release for 6 months of public consultation (EMEA/CVMP/790/03-CONSULTATION)

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

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The Committee was informed of the major outcomes of the VICH Steering Committee, which took place in Washington on 6-8 October 2003 where the above-mentioned guideline was signed-off for public consultation.

The Steering Committee acknowledged the completion of the mandate by the Expert Working Group on Antimicrobial Resistance. The VICH draft GL 27 (Guidance on Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food Producing Animals with respect to Antimicrobial Resistance) will be presented to the Steering Committee for signing-off by written procedure.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSUR) for **Incurin** and **Metacam** and concluded that no changes to the product literature or other regulatory actions were required.

Biotech

The Committee adopted the Revised Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMEA/410/01-Rev.2). The guideline is scheduled for adoption by the CPMP at the October meeting (21-23 October 2003) and will then be forwarded to the Commission for publication.

Immunologicals

The Committee adopted the Guideline on requirements for concurrent administration of immunological veterinary medicinal products (EMEA/CVMP/550/02-FINAL) following the close of the consultation period.

The Committee also adopted the Position Paper on Data Requirements for Removing the Target Animal Batch Safety Test for Immunological Veterinary Medicinal Products in the EU (EMEA/CVMP/865/03-CONSULTATION) for release for 3 months of public consultation.

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

Enlargement/Pre-Accession Linguistic Checking Process

As the Community enters into the final months of the preparatory period prior to the enlargement of the EU, the Committee was informed about the publication of the details of the pre-accession linguistic checking process on the enlargement section of the EMEA webpage (http://www.emea.eu.int/euenlargement.htm). This process addresses the obligation of all Marketing Authorisation Holders to provide translations of the product information in the new official languages as of the date of accession. All Marketing Authorisation Holders of centralised veterinary products are invited to take part in this checking process in order to ensure the timely preparation of the product information prior to enlargement. They are therefore invited to provide the EMEA with translations from now onwards. It was stressed that translations will be essential to processing any post-enlargement variation and line-extension opinions for centrally authorised products.

Organisational issues

The Committee agreed the agenda of the Informal CVMP to be held in Rome on 24-25 November 2003 which will focus on discussion of the following points: implications of the review of EU legislation on pharmaceuticals, enlargement of the EU – impact on CVMP organisation, quality of CVMP Assessment Reports and functioning and organisation of the Strategic Planning Group.

The next meeting of the CVMP will be held on 11-13 November 2003

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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

	1995-2002	2003	Overall Total
Applications submitted	50	6	56
Withdrawals	8	1	9
Positive CVMP opinions	38	2	40
Negative CVMP opinions[1]	0	0	0

Variations

	1995-2002	2003	Overall Total
Variations type I	98	43	141
Variations type II	37	10	47

Extensions

	1995-2002	2003	Overall Total
Extensions (Annex II applications) submitted	33	2	35
Withdrawals	1	0	1
Positive opinions	15	5	20
Negative opinions	0	0	0

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

Renewals of marketing authorisations

	1995-2002	2003	Overall Total
Renewal applications submitted	7	2	9
Renewal positive opinions	5	4	9
Renewal negative opinions	0	0	0

Scientific advice

	1995-2002	2003	Overall Total
Applications submitted	20	1	21

Establishment of maximum residue limits

	1995-2002			2003			Overall Total
	Full	Extension/ Modification	Total	Full	Extension/ Modification	Total	
Applications submitted	50	73	123	1	7	8	131
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	36	79	115	1	4	5	120
Negative opinions**	5	5	10	0	0	0	10

*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

	1995-2002	2003	Overall Total
Referrals	7	1	8