



European Medicines Agency
Veterinary Medicines and Inspections

London, 16 July 2004
EMEA/CVMP/713/04

PRESS RELEASE
COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
Meeting of 13 to 15 July 2004

Maximum Residue Limits

The Committee adopted, by consensus, a positive opinion recommending the establishment of provisional maximum residue limits for acetylisovaleryltylosin in poultry. The application procedure was initiated on 16 April 2004 and the opinion was adopted on 14 July 2004 with an active review time of 90 days.

The Committee adopted an opinion by consensus recommending the extension of the current Annex I entry of Council Regulation (EEC) No. 2377/90 for moxidectin to include sheep milk. The application procedure was initiated on 19 March 2004 and the opinion was adopted on 14 July 2004 with an active review time of 90 days.

The Committee adopted an opinion by consensus recommending the extension of the current Annex II entry for linear alkyl benzene sulphonic acids to sheep further to a request from two companies.

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

Scientific advice

The Committee established a Scientific Advice Working Party set up in accordance with the legal requirements of Title IV of Regulation (EC) No 726/2004 and appointed Professor R Kroker as chairman. The mandate and membership of the Scientific Advice WP will be published on the EMEA web site.

The Committee agreed follow-up scientific advice regarding the clinical development of an oncology product for treating mast cell tumours in dogs.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for Eurican Herpes 205, Eurifel RCP FeLV, Ibraxion, Proteq Flu, Incurin, Pirsue and concluded that no further action or changes to the product literature of the products were required. The Committee also reviewed the PSURs for Eurifel RCP FeLV and Proteq Flu-Te, however no final conclusions were taken and the MAHs were invited to comment on questions that had arisen during the assessment of the PSURs.

The Committee adopted a revision of the Guideline on Data Elements for the electronic submission of ADRs to veterinary medicinal products authorised in the European Economic Area (EEA) (EMEA/CVMP/065/03-Rev.2) including message and transmission specifications, implementing changes received following the testing phase and training modules with EudraVigilance Veterinary in collaboration with Member States' users and Veterinary pharmaceutical industry representatives.

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This version will be the basis for the update of EudraVigilance Veterinary that will go in production from 1 September 2004. The corresponding technical guideline on EudraVigilance Veterinary XML Schema Definition (XSD) and Veterinary Acknowledgement XSD will be amended and released shortly.

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

Antimicrobials

The CVMP confirmed the establishment and endorsed the mandate of the newly created Scientific Advisory Group on Antimicrobials. The group includes acknowledged experts from throughout the European Union and will provide expertise to the CVMP on all matters relating to antimicrobial substances and will be chaired by Dr L Kaartinen, member from Finland. The group will also be advising the CVMP on critical aspects in relation to the evolving situation and trends on antimicrobial resistance in the EU. The endorsed mandate and workprogramme of the group, including its composition will be published on the EMEA web site.

Guidelines

Efficacy

The Committee adopted the following guideline prepared by the Efficacy Working Party, following the close of the consultation period:

- Specific efficacy requirements for ectoparasiticides in cattle (EMEA/CVMP/625/03).

The Committee adopted the following concept paper prepared by the Efficacy Working Party with a consultation period of 3 months:

- SPC guidance to minimise the development of anthelmintic resistance (EMEA/CVMP/638/04).

Quality

The Committee adopted the following guidelines prepared by the Joint CPMP/CVMP Quality Working Party, following the close of their consultation periods:

- CVMP Guideline on Quality Aspects of Pharmaceutical Veterinary Medicines for Administration via Drinking Water (EMEA/CVMP/540/03).
- Joint CHMP/CVMP Guideline on the Summary of Requirements for Active Substances in the Quality Part of the Dossier (EMEA/CVMP/1069/02).

Immunologicals

The Committee adopted the following guidelines prepared by the Immunologicals Working Party, following the close of their consultation periods:

- CVMP Revised Guideline on Requirements and Controls applied to Bovine Serum used in the Production of Immunological Veterinary Medicinal Products (EMEA/CVMP/743/00-Rev.1).
- CVMP Position Paper on data requirements for removing the target animal batch safety test for Immunological Veterinary Medicinal Products in the EU (EMEA/CVMP/865/00-FINAL).

Safety

The Committee adopted the Revised Position Paper on the definition of substances capable of pharmacological action in the context of Council Directive 2001/82/EC (EMEA/CVMP/072/97-Rev.1). The Position Paper established the principle on how to interpret the legal requirement that all pharmacologically active substances contained in a veterinary medicinal product intended for food producing animals should be included in Annex I, II or III of Regulation 2377/90 in respect to excipients. This revision is an update to accommodate the new legislative references, and also clarifies the approach to be taken for manufacturing materials with regard to the establishment of MRLs. Further considerations are still ongoing with regard to adjuvants and the present text will be revised once the approach regarding adjuvants has been finalised.

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

Availability

The Committee adopted the CVMP Position Paper on the availability of products for Minor Uses and Minor Species (MUMS) (EMEA/CVMP/477/03-FINAL) following its review and revision to take account of the comments made during the public consultation and to take into account the new legal provisions in the review of the pharmaceuticals legislation. The consultation had resulted in a wide range of comments from Interested Parties and the feedback to the CVMP proposals for the way ahead regarding availability had been mostly positive. Specific proposals in respect to data requirements for dossiers for MUMS products are being addressed separately. Work on this has been advanced by the CVMP Working Parties and proposals are being finalised and expected to be released for consultation in the near future.

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

The Committee considered a proposal from the Federation of Veterinarians of Europe (FVE) on a gap list of 12 essential substances for therapy that had been submitted earlier this year. The CVMP, in consultation with the Veterinary Mutual Recognition Facilitation Group (VMRFG), reviewed in particular whether any products containing the essential substances would be authorised in Member States or whether alternatives regarding the identified substances would be available. A reply to FVE with the information gathered from the regulatory authorities in the EU is being finalised together with the VMRFG.

International harmonisation

VICH

The Committee reviewed the two draft VICH quality guidelines on specifications for pharmaceuticals and biologicals, which are both based on the respective ICH guidelines Q6A and Q6B:

- VICH GL39 on Test procedures and Acceptance of Criteria for New Veterinary Drug Substances and New Medicinal Products
- VICH GL40 on Test procedures and Acceptance of Criteria for New Biotechnical/Biological Veterinary Medicinal Products.

The Committee endorsed their sign-off by the EU VICH Steering Committee members at step 3 for public consultation. Provided the VICH Steering Committee's sign-off, which is expected for the end of July 2004, the guidelines would be published for consultation in the EU in August 2004.

Codex Alimentarius

The Committee reviewed the Codex Circular Letter 2004/17-RVDF and agreed on comments on the draft Codex MRLs proposed by JECFA at its 60th and 62nd meeting, in preparation of the EU comments at the 15th Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF). The Committee agreed on comments on proposed MRLs for neomycin (MRLs in bovine tissues and milk), imidocarb (MRLs in bovine tissues and milk), dicyclanil (MRLs in ovine tissues), trichlorfon (MRLs in bovine tissues and milk), carbadox (MRLs in porcine tissues), cefuroxime (MRLs in bovine milk), flumequine (MRLs for cattle, sheep, porcine, shrimps, chicken and trout tissues), lincomycin (MRLs for bovine tissues), pirlimycin (MRLs for bovine tissues and milk), cyhalothrin (MRLs for bovine, ovine, porcine tissues and bovine milk), cypermethrin and alphacypermethrin (MRLs for bovine and ovine tissues and bovine milk), doramectin (MRLs for bovine milk), phoxim (MRLs for caprine tissues), melengestrol acetate (MRLs for bovine tissues) and ractopamine (MRLs for bovine and porcine tissues). These comments will be sent to the European Commission to serve as basis for EU comments to be endorsed by EU Member States.

The next meeting of the CVMP will be held on 7-9 September 2004

Peter G.H. Jones

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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 July 2004

Marketing Authorisations

	1995-2003	2004	Overall Total
Applications submitted	60	7	67
Withdrawals	9	1	10
Positive CVMP opinions	42	4	46
Negative CVMP opinions¹	0	0	0

Variations

	1995-2003	2004	Overall Total
Variations type I	146	11	157
Variations type II	49	5	54
Transfers	4	1	5

Extensions

	1995-2003	2004	Overall Total
Extensions (Annex II applications) submitted	35	4	39
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	3	14
Renewal positive opinions	9	2	11
Renewal negative opinions	0	0	0

Scientific advice

	1995-2003	2004	Overall Total
Applications submitted	22	4	26

Establishment of maximum residue limits

	1995-2003			2004			Overall Total
	Full	Extension/ Modification	Total	Full	Extension/ Modification	Total	
Applications submitted	52	81	133	3	4	7	140
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	37	86	123	7	3	10	133
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	2	10