



PRESS RELEASE
COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
Meeting of 15 to 17 June 2004

The new Committee held its first meeting following the entry into force of parts of the new pharmaceutical legislation and elected Dr. Gérard Moulin, from France as its chairman and Dr. Johannes Hoogland from The Netherlands as vice-chairman. The Committee is composed of one member per Member State from all 25 countries within the European Union and one member from Iceland and Norway.

On this occasion the Committee adopted its Rules of Procedure taking into account the provisions of the new legislation in particular the new composition of the Committee with alternates and the possibility for up to five co-opted members, subject to the agreement of the European Commission and of the Management Board of the Agency. The Rules of Procedure will be published once they have been agreed by the Commission and the Management Board.

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted, by consensus, a positive opinion on an initial marketing authorisation application for Previcox from Merial. Previcox contains firocoxib as the active substance and is intended for the relief of pain and inflammation associated with osteoarthritis in dogs. The application procedure was initiated on 18 June 2003 and the opinion was adopted on 16 June 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>

Maximum Residue Limits

The Committee adopted, by consensus, a positive opinion recommending the inclusion of beclometasone dipropionate in Annex II of Council Regulation (EEC) No. 2377/90 for horses. The application procedure was initiated on 19 March 2004 and the opinion was adopted on 16 June 2004 with an active review time of 90 days.

The Committee adopted, by consensus, a positive opinion recommending the establishment of provisional maximum residue limits for toltrazuril for cattle (non-lactating). The application procedure was initiated on 19 March 2004 and the opinion was adopted on 16 June 2004 with an active review time of 90 days.

The Committee adopted, by consensus, a positive opinion recommending the inclusion of altrenogest in Annex I of Council Regulation (EEC) No. 2377/90 for porcine and Equidae species further to the establishment of provisional MRLs.

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

Community Referrals

The Committee considered the notification for a referral under article 35 of Council Directive 2001/82/EC, as amended, for Micotil 300 (tilmicosin) from France. The referral was initiated following a human fatality that occurred in the USA earlier this year. The product concerned by this referral is authorised nationally in 16 Member States. A rapporteur and a co-rapporteur were appointed and a list of questions to be sent to the Marketing Authorisation Holders, to be responded to within 3 months, was agreed.

Antimicrobial resistance

The Committee confirmed the establishment of the new Scientific Advisory Group on Antimicrobials. The group was recently proposed for continuing the CVMP's strategic assessment and management of resistance in relation to the authorisation of antimicrobial veterinary medicinal products. The group will provide expertise to the CVMP on all matters relating to antimicrobial resistance, and when necessary the provision of advice in the authorisation of veterinary medicinal products. The group will meet for the first time on 24 June 2004.

Transmissible Spongiform Encephalopathy (TSE)

The Committee endorsed the proposal from the Biotech Working Party to amend sections 6.2 (gelatin) and 6.3 (bovine blood derivatives) of revision 2 of TSE Note for Guidance following the recommendations from the TSE expert meeting convened at the EMEA on 30 March 2004 to discuss the matter in light of the first cases of BSE reported in Canada and USA and in particular the concerns relating to gelatin, bovine blood derivatives and other ruminant materials from GBR III countries. The recommendation was adopted by the CHMP on 2 June 2004 and will be published on the EMEA web site for a 2-month public consultation.

Pharmacovigilance

The Committee adopted the draft guideline on triggering pharmacovigilance investigations prepared by the Pharmacovigilance Working Party for release for a 6-month period of consultation (EMEA/CVMP/900/03-CONSULTATION). This guideline is addressed to Competent Authorities, and, provides advice on decision points that are considered useful standards for initiating such investigations as well as on essential steps that should be part of such investigations. The guideline aims to harmonise the approach taken by Member States to investigate pharmacovigilance events but is not intended to infringe on the Authorities' competence to trigger investigations.

The Committee adopted the guideline on additional controlled terminology for electronic submission of reports on adverse reactions to veterinary medicinal products for release for a 3-month period of consultation (EMEA/CVMP/556/04-CONSULTATION). This guideline on additional fields is complementary to the previously published list of species and breeds (EMEA/CVMP/553/03) and is a further step towards the implementation of electronic submission of adverse reaction reports of veterinary medicines in the European Union. Since the European veterinary pharmaceutical industry had been previously consulted during the drafting process, a shorter than usual consultation period was considered adequate.

The Committee adopted the Concept Paper for the Simple guide to veterinary pharmacovigilance in the European Union for release for a 2-month consultation (EMEA/CVMP/557/04-CONSULTATION). This concept paper introduces the CVMP project and the envisaged process for developing a general user-friendly guide on veterinary pharmacovigilance in the European Union for the animal health profession (in particular veterinarians, veterinary nurses, pharmacists).

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

Immunologicals

The Committee adopted a Position Paper on requirements for vaccines against Foot-and-Mouth Disease (EMEA/CVMP/775/02-FINAL) following the close of the consultation period. This position paper considers the scientific issues raised by Foot-and-Mouth Disease vaccines and proposes methods that can be used to demonstrate that vaccines meet the necessary technical standards such that they are suitable for authorisation. Foot-and-Mouth Disease vaccines represent a 'special' case in terms of the need for rapid and constant change in the included strains. The objective of this position paper is to clarify the requirements that must be met for a Foot-and-Mouth Disease vaccine to obtain a marketing authorisation and to be released as an authorised product.

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

Quality issues

The Committee adopted a revised joint guideline prepared by the Joint CHMP/CVMP Quality Working Party on the Summary of Requirements for Active Substances in the Quality Part of the dossier. Publication of this joint guideline will follow its final adoption by the CHMP, which is foreseen for their next meeting on 21-24 June 2004.

Availability

The Committee discussed the draft of the CVMP Position Paper on the availability of products for Minor Uses and Minor Species (MUMS) that has been further revised to consider the comments made during the CVMP discussion following the public consultation and to take into account the new legal provisions in the review of the pharmaceuticals legislation. The document is intended to be finalised at the July 2004 meeting.

International harmonisation

The Committee adopted the VICH GL36 on studies to evaluate the safety of residues of veterinary drugs in human food: General approach to establish a microbiological ADI (CVMP/VICH/467/03-FINAL). The guideline will enter into effect in May 2005.

The Committee adopted the VICH GL37 on studies to evaluate the safety of residues of veterinary drugs in human food: Repeat-dose Chronic Toxicity Testing (CVMP/VICH/468/03-FINAL). Also this guideline will enter into effect in May 2005.

The Committee adopted the editorial changes for the following VICH guidelines:

- VICH GL22 on studies to evaluate the safety of residues of veterinary drugs in human food: Reproduction testing (CVMP/VICH/525/04)
- VICH GL23 on studies to evaluate the safety of residues of veterinary drugs in human food: Genotoxicity Testing (EMEA/CVMP/VICH/526/04)
- VICH GL31 on studies to evaluate the safety of residues of veterinary drugs in human food: Repeat-dose (90 days) Toxicity Testing (CVMP/VICH/484/04)
- VICH GL32 on studies to evaluate the safety of residues of veterinary drugs in human food: Development Toxicity Testing (EMEA/CVMP/VICH/485/04)

- VICH GL33 on studies to evaluate the safety of residues of veterinary drugs in human food: General Approach to Testing (CVMP/VICH/486/04)

These changes were made following completion of the set of VICH safety guidelines and the review of previous agreed texts regarding consistency, updates of references and formatting. They amended guidelines will replace the previous documents.

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

Organisational issues

The Committee adopted the procedure for the nomination and appointment of co-opted members and initiated discussion on the additional specific expertise required to complement the existing scientific expertise. A decision on the required expertise will be finalised within 3-months. Members will propose experts corresponding to the scientific expertise identified and a selection by election will take place during subsequent meetings.

The Committee established the following working parties as standing working parties in addition to the Scientific Advice Working Party:

- Pharmacovigilance Working Party,
- Efficacy Working Party,
- Immunologicals Working Party,
- Safety Working Party, and
- Joint CHMP/CVMP Quality Working Party.

The previous ad hoc group on Environmental Risk Assessment was now established as a temporary working party and the establishment the Scientific Advisory Group on Antimicrobials was confirmed. The Committee considered that at present no further scientific advisory groups were justified.

The Committee agreed to maintain the current Chairpersons of the working parties until the full CVMP is established with the appointment of the co-opted members, before a new election for chairpersons of the working parties is held.

The Committee also agreed that the current format/composition and appointment of experts of the working parties would be revisited following the inclusion of experts from the new Member States following the EU enlargement. Subsequently, new mandates for the working parties will be adopted and published.

The Committee reviewed the rapporteurship for the different application procedures in light of the new composition of the Committee. Applicants will be informed of the new rapporteurs, if appropriate.

The Committee agreed the procedure to be followed to facilitate communication and dialogue between the CVMP and the interested parties for release for a 3-month period of consultation (EMEA/CVMP/329/04-CONSULTATION).

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

EMEA-IFAH Europe Info day

Following the CVMP meeting an Info day with Interested Parties was held on 17 and 18 June 2004. The meeting was divided in two parts, the first one, on 17 June to discuss “*The European Medicines Agency Roadmap to 2010*” and the second one, organised as a “*Focus group*” with the participation of CVMP Safety experts and Interested parties to discuss injection site residues, and will be reported separately.

The next meeting of the CVMP will be held on 13-15 July 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>

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NOTES

1. Gérard Moulin (France) is a biologist specialising in microbiology and cellular biology. He is currently Director Delegate International Affairs at the National Agency for Veterinary Medicinal Products in France. He was appointed a member of the CVMP in March 1997 and first elected as chairman in January 2003.
2. Johannes Hoogland (Netherlands) is a chemist specialising in analytical chemistry, biochemistry and quality management. He is currently technical secretary responsible for medicinal feed additives and veterinary medicines at the Agency for the Registration of Veterinary Medicinal Products at the Ministry of Agriculture, Nature and Food Quality in the Netherlands.
3. The Committee for Medicinal Products for Veterinary Use (CVMP) replaces the Committee for Veterinary Medicinal Products. A list of the new CVMP membership can be found at the EMEA web site (<http://www.emea.eu.int>).
4. A photograph of the new chairman and vice-chairman is available from the EMEA web site or from the Press Office. Individual photographs of the chairman and vice-chairman are also available.
5. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at the following location: <http://www.emea.eu.int>

Annex I to CVMP Press Release June 2004

Marketing Authorisations

	1995-2003	2004	Overall Total
Applications submitted	60	6	66
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	10	156
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	0	11
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	2	4	6	139
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	37	86	123	6	2	8	129
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