14 January 2014
EMA/CVMP/31508/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Minutes of the 208th CVMP meeting of 10 - 12 December 2013

Committee for Medicinal Products for Veterinary Use (CVMP)

The meeting was chaired by A. Holm.

Disclaimers

Some of the information contained in these minutes is considered commercially confidential and therefore is not disclosed. The procedures discussed by the CVMP are on-going and therefore certain aspects are considered confidential. Documents mentioned in the minutes cannot be released at present (unless otherwise stated) as they are currently in draft format or are classified as confidential. Some documents will become public when adopted in their final form or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

1. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

2. CVMP delegates' list of intended participation and identified conflicts of interests with regards to agenda items

The attendance list was completed and conflicts of interests were identified for the December 2013 meeting, see Annex I. The Chair welcomed F. Hasslung Wikström, the new alternate member from Sweden.

Discussions, deliberations and voting have taken place in full respect of the restricted involvement as announced by the Committee secretariat. It was noted that 22 members were needed for a quorum and 18 for an absolute majority.

3. Declaration of contacts between members and companies with regard to points on the agenda

Information relating to declared contacts between members and companies with regard to points on the agenda cannot be released at present time as it is deemed to be commercially confidential.

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4. Adoption of the minutes of the previous meeting

The minutes of the November 2013 meeting were adopted with no amendments.

5. Topics for rapporteur's meetings, break-out sessions and oral explanations

Information relating to briefing meetings taking place with applicants cannot be released at present time as it is deemed to be commercially confidential.

A – ADOPTION OF OPINIONS/LIST OF QUESTIONS

A.1 ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

A.1.1 Opinions on applications

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report for the establishment of MRLs for **cabergoline** in bovine species (EU/V/202/CEV). The Icelandic and Norwegian CVMP members agreed with the above mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending final MRLs for **clorsulon** (EU/ART27/11/190/IMB) in bovine milk further to the extrapolation and establishment of provisional MRLs in milk. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.
- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending final MRLs for **closantel** (EU/ART27/11/191/IMB) in bovine and ovine milk further to the extrapolation and establishment of provisional MRLs in milk. The Icelandic and Norwegian CVMP members agreed with the above mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.
- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report for the modification of ADI and MRLs for **lasalocid** (EU/12/204/PFZ). The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report for the application for the establishment of MRLs for **lufenuron** in salmonidae (EMEA/V/MRL/003749/FULL/0001). The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.
- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report for the extrapolation of the current MRLs for **rafoxanide** (EU/ART27/11/192/IMB) to bovine and ovine milk. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

- The Committee adopted the CVMP status report and list of questions for the extension of MRLs for a substance to porcine species (EMEA/V/MRL/003158/EXTN/0002) after discussing the rapporteur's revised assessment report, the EU-RL report, a peer review report and the comments received from CVMP members.

A.1.2 Recommendations for extrapolation of established MRLs

- There were no items for discussion.

A.1.3 Re-examination of CVMP opinions

- There were no items for discussion.

A.2 COMMUNITY MARKETING AUTHORISATIONS

A.2.1 Opinions on applications

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Contacera** (EMEA/V/C/002612/X/0002), recommending the extension of the marketing authorisation to include a new pharmaceutical form for horses, meloxicam 15 mg/ml. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a new product, **Bravecto** (EMEA/V/C/002526/0000), recommending the granting of a marketing authorisation. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The product is an ectoparasiticide containing fluralaner, intended for the treatment of tick and flea infestations in dogs. The Committee noted the summary of opinion for publication.

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a new product, **NexGard** (EMEA/V/C/002729/0000), recommending the granting of a marketing authorisation. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The product is an ectoparasiticide containing afoloxaner, intended for the treatment of tick and flea infestations in dogs. The Committee noted the summary of opinion for publication.

A.2.2 Variations to Community marketing authorisations

- The Committee adopted the CVMP list of questions for a type II variation for **AFTOVAXPUR DOE** (EMEA/V/C/002292/II/0001), concerning the addition of a new virus antigen strain.

- The Committee adopted the CVMP list of questions for a worksharing type II quality variation for **EQUIOXX** (EMEA/V/C/000142/WS/0474/G) and **Previcox** (EMEA/V/C/000082/WS/0474/G).

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a worksharing quality variation for **Fevaxyn Pentofel** (EMEA/V/C/000030/WS/0470), recommending the variation of the marketing authorisation. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped worksharing quality variation for **Fevaxyn Pentofel** (EMEA/V/C/000030/WS/0471/G), recommending the variation of the marketing authorisation. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped worksharing quality variation for **Metacam (**EMEA/V/C/000033/WS/0473/G) and **Novem** (EMEA/V/C/000086/WS/0473/G), recommending the variation of the marketing authorisations. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped worksharing quality variation for **Metacam** (EMEA/V/C/000033/WS/0447/G) and **Novem** (EMEA/V/C/000086/WS/0447/G), recommending the variation of the marketing authorisations. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

A.2.3 Re-examination of CVMP opinions

- There were no items for discussion.

A.2.4 Lists of questions

- There were no items for discussion.

A.3 REFERRALS AND RELATED PROCEDURES

A.3.1 Article 33 of Directive 2001/82/EC

- The Committee heard an oral explanation from the MAH, Vet-Agro Trading Sp. z o.o., and adopted by majority (20 members in favour out of the 29 present of those eligible to vote) the CVMP opinion and CVMP assessment report for the referral procedure for **Fiprex CAT 52.5 mg spot-on solution for cats, Fiprex S 75 mg spot-on solution for dogs, Fiprex M 150 mg spot-on solution for dogs, Fiprex L 300 mg spot-on solution for dogs and Fiprex XL 412.5 mg spot-on solution for dogs** (EMEA/V/A/099), concluding that the application does not meet the requirements laid down by Article 13a of Directive 2001/82/EC and consequently does not satisfy the criteria for marketing authorisation in respect of efficacy. Therefore, the Committee recommended the refusal of the granting of the marketing authorisations and the suspension of the existing marketing authorisations for the above mentioned veterinary medicinal products. T. Soós, S. Spiteri, P. Hekman, B. Zemann, E. Augustynowicz, S. Srčič, B. Kolar, I. Malemis, and J. Bureš signed a divergent position. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee discussed the rapporteur's assessment report with the co-rapporteur's critique for the referral procedure for **Norbonex 5 mg/ml pour-on solution for beef and dairy cattle** (EMEA/V/A/098). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the January 2014 meeting of the Committee.

A.3.2 Article 34 of Directive 2001/82/EC

- There no items for discussion.

A.3.3 Article 35 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment report with the co-rapporteur's critique for the referral procedure for **Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names, and related veterinary medicinal products authorised under Article 13 of Directive 2001/82/EC** (EMEA/V/A/097). The Committee adopted a list of outstanding issues for the applicants/marketing authorisation holders to address in writing and a revised timetable for the procedure.

A.3.4 Article 39 of Directive 2001/82/EC

- There were no items for discussion.

A.3.5 Article 13 of Regulation (EC) No 1234/2008

- There were no items for discussion.

A.3.6 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

A.3.7 Article 30(3) of Regulation 726/2004

- There were no items for discussion.

A.3.8 Article 45 of Regulation 726/2004

- There were no items for discussion.

A.3.9 Miscellaneous items

- There were no items for discussion.

B - MARKETING AUTHORISATION APPLICATIONS FOR DISCUSSION AND DECISION

- The Committee heard an oral explanation from ECO Animal Health, concerning an extension application for **Aivlosin** (EMEA/V/C/00083/X/0055) to add a new pharmaceutical form. The Committee also discussed the draft product information. An opinion is foreseen for the January 2014 CVMP meeting.
- The Committee discussed the draft product information for a marketing authorisation application for a new respiratory product for horses (EMEA/V/C/002382/0000). An opinion is foreseen for the January 2014 CVMP meeting.
- The Committee heard an oral explanation from MSD Animal Health, concerning an extension application for **Panacur Aquasol** (EMEA/V/C/002008/X/0003) to add a new target species, chickens. The Committee also discussed the draft product information. An opinion is foreseen for the January 2014 CVMP meeting.
- The Committee discussed the draft product information and the draft CVMP assessment report for a marketing authorisation application for a new antifungal product for avian species (EMEA/V/C/002722/0000).
- The Committee adopted the updated scientific overview and benefit-risk assessment and the list of outstanding issues, and discussed the draft product information and the QRD comments for a marketing authorisation application for a new product (EMEA/V/C/002746/0000), an ectoparasiticide for cats. The Committee agreed that an oral explanation would be necessary. The Committee noted a peer review report and the comments from CVMP members.

- The Committee adopted the updated scientific overview and benefit-risk assessment and the list of outstanding issues, and discussed the draft product information for a marketing authorisation application for a new product (EMEA/V/C/002759/0000), a live and inactivated viral and bacterial vaccine for dogs. The Committee agreed that an oral explanation would not be necessary. The Committee noted two peer review reports and the comments from CVMP members.
- The Committee agreed to a request from the applicant for the extension of the timeframe for the submission of responses to the list of questions for a marketing authorisation application for a new product (EMEA/V/C/002808/0000), a hormonal preparation for use in cats.
- The Committee noted the correspondence regarding the ongoing procedure for a new product (EMEA/V/C/002390/0000), concerning a vaccine for use in Atlantic salmon.

C – POST-AUTHORISATION ISSUES (EXCLUDING VARIATIONS)

C.1 General issues

- The Committee noted the quality defect and recall of all marketed batches for **RevitaCam** (EMA/INS/GMP/781777/2013).

C.2 Specific obligations and follow up measures to CVMP opinions on the granting of Community marketing authorisations

- There were no items for discussion.

C.3 Product anniversary list (previously annual reports)

- The Committee noted the product anniversary list for the period between 11 November 2012 to 10 December 2013:
  - **Acticam** (EMEA/V/C/000138) – 09 December 2012 – 08 December 2013
  - **Contacera** (EMEA/V/C/002612) – 06 December 2012 – 05 December 2013
  - **DRAXXIN** (EMEA/V/C/000077) – 11 November 2012 – 10 November 2013
  - **Easotic** (EMEA/V/C/000140) – 20 November 2012 – 19 November 2013
  - **Equip WNV** (EMEA/V/C/000137) – 21 November 2012 – 20 November 2013
  - **Inflacam** (EMEA/V/C/002497) – 9 December 2012 – 8 December 2013
  - **Masivet** (EMEA/V/C/000128) – 17 November 2012 – 16 November 2013
  - **Meloxivet** (EMEA/V/C/000124) - 17 November 2012 – 16 November 2013
  - **Meloxoral** EMEA/V/C/000151) – 19 November 2012 – 18 November 2013
  - **Oxyglobin** (EMEA/V/C/000045) – 29 November 2012 – 28 November 2013
  - **Panacur AquaSol** (EMEA/V/C/002008) – 9 December 2012 – 8 December 2013
  - **Porcilis AR-T DF** (EMEA/V/C/000055) – 16 November 2012- 15 November 2013
  - **Quadrisol** (EMEA/V/C/000032) – 04 December 2012 – 03 December 2013
  - **SevoFlo** (EMEA/V/C/000072) – 11 December 2012 – 10 December 2013
  - **Stronghold** (EMEA/V/C/000050) – 25 November 2012 – 24 November 2013
  - **Virbagen Omega** (EMEA/V/C/000061) – 06 November 2012 – 05 November 2013

C.4 Renewals of marketing authorisations

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the renewal of **STARTVAC** (EMEA/V/C/000130/R/0001). The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. It was agreed that the authorisation should now be indefinite.
- The Committee adopted a list of outstanding issues concerning the renewal application for **BTVPUR AlSap 8** (EMEA/V/C/000146/R/0010).
- The Committee adopted a list of questions concerning the renewal application for **Loxicom** (EMEA/V/C/000141/R/0018).

C.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP PSUR assessment report for **Leucogen** (EMEA/V/C/000144) for the period 01.02.2012 – 30.06.2013 and concluded that amendments to the product information were required to include reference to the frequency of existing adverse reactions already in the product information.
- The Committee discussed the concerns raised by the MAH relating to the outstanding issues for the targeted PSUR for **Comfortis** for the period 11/02/2011 - 31/03/2013 and endorsed a response letter to the company with regard to further information required for the finalisation of the assessment of the PSUR.
- The Committee adopted the following CVMP PSUR assessment reports concluding that no changes to the product literature or other regulatory actions were required at this stage for:

Product	**Period**
Activyl Tick Plus (EMEA/V/C/002234)	01.02.2013-31.07.2013
Cimalgex (EMEA/V/C/000162)	01.03.2013-31.08.2013
Emdocam (EMEA/V/C/002283)	01.03.2013-31.08.2013
Reconcile (EMEA/V/C/000133)	01.02.2013-31.07.2013
Rheumocam (EMEA/V/C/000121)	01.02.2013-31.07.2013
STARTVAC (EMEA/V/C/000130)	01.09.2012-31.08.2013
Suvaxyn PCV (EMEA/V/C/000149)	01.02.2013-31.07.2013
ZULVAC 8 Bovis (EMEA/V/C/000145)	01.02.2013-31.07.2013
ZULVAC 8 Ovis (EMEA/V/C/000147)	01.02.2013-31.07.2013

- The Committee endorsed the list of products and calendar for signal detection analysis.

C.6 Supervisions and sanctions

- There were no items for discussion.

D – CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

D.1 VICH

- The Committee endorsed the draft VICH GL52 on Bioequivalence: blood level bioequivalence study for release for consultation (EMA/CVMP/VICH/751935/2013).
- The Committee endorsed the draft VICH GL53 on electronic file formats: sign-off by VICH Steering Committee at step 3 for release for consultation at step 4 (EXT/758781/2013).

- The Committee endorsed the implementation date of 31 December 2015 for the VICH GL24 on Pharmacovigilance: Management of ADRs (the guideline was previously adopted and published in 2008) (EMA/CVMP/VICH/547/2000).
- The Committee endorsed the implementation date of 31 December 2015 for the VICH GL30 on Pharmacovigilance: controlled list of terms (the guideline was previously adopted and published in 2010) (EMA/CVMP/VICH/647/2001).
- The Committee endorsed the implementation date of 31 December 2015 for the VICH GL35 on Pharmacovigilance: electronic standards for transfer of data (the guideline was previously adopted and published in March 2013) (EMA/CVMP/VICH/123940/2006).
- The Committee endorsed the implementation date of 31 December 2015 for the VICH GL42 on Pharmacovigilance: data elements for submission of adverse event reports (the guideline was previously adopted and published in 2010) (EMA/CVMP/VICH/355996/2005).
- The Committee received a verbal report on the VICH Steering Committee meeting held on 11-14 November 2013 in Auckland, New Zealand.

D.2 Codex Alimentarius

- There were no items for discussion.

D.3 Other EU bodies and international organisations

- The Committee endorsed the EFSA opinion on the bovine tuberculosis vaccination and noted the comments made.
- The Committee endorsed the appointment of E. Werner as the CVMP IWP representative to the EDQM Steering Committee of the Biological Standardisation Programme.

The following document was circulated for information:

- Status of VICH Guidelines and meeting schedule of the VICH Expert Working Groups.

E - WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

E.1 Scientific Advice Working Party (SAWP)

Information relating to SAWP procedures cannot be released at the present time as it is deemed to be commercially confidential.

E.2 Pharmacovigilance Working Party (PhVWP)

- The Committee adopted the reflection paper on pharmacovigilance communication concerning veterinary medicinal products and the overview of comments received.
- The Committee endorsed the recommendation on pharmacovigilance surveillance and signal detection of veterinary medicinal products.
- The Committee re-elected Peter Ekström as chairperson of the PhVWP for a further 3-year mandate with 27 votes (2 abstained).
- The Committee received a verbal report from the PhVWP meeting held on 26-27 November 2013 and noted the agenda and the draft minutes of the meeting.
- The Committee received feedback from the Agency on the workshop on harmonising the approach to VeDDRA coding.

E.3 Efficacy Working Party (EWP)

- The Committee noted the revised guideline for the conduct of efficacy studies for non-steroidal anti-inflammatory drugs and the overview of comments received from interested parties. The guideline is expected for adoption in January 2014.
- The Committee received a verbal report from the chair of the EWP on the meeting held on 3-4 December 2013 and noted the draft minutes of the meeting.
- The Committee received a verbal report from G. Hahn from the Focus Group Meeting that was held on 9 December 2013 on the revision of the CVMP Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances.

E.4 Safety Working Party (SWP-V)

- The Committee adopted the mandate, objectives and rules of procedure for the CVMP Safety Working Party for another period of 3 years. The content of the mandate remains unchanged.
- The Committee elected Eva Lander Persson as chairperson of the SWP for a 3-year mandate with 27 votes in favour (2 abstentions).
- The Committee received a verbal report from the vice chair of the SWP-V on the meeting held on 28-29 November 2013 and noted the agenda of the meeting.
- The Committee discussed the draft reflection paper on the methodology for use in user safety risk assessment of flea collars containing dimpylate, propoxur and tetrachlorvinphos, which had been prepared on the basis of the limited advice given to the CMDv in relation to risk assessments by member states related to collars containing these substances. The Committee considered the suggestion from the SWP-V that a guideline should be developed on user safety risk assessment of topically applied veterinary medicinal products for companion animals and agreed to request the SWP-V to develop a concept paper on this topic. In view of this activity the Committee concluded that it would be preferable not to publish the draft reflection paper, which had been prepared in relation to a very specific case.

E.5 Immunologicals Working Party (IWP)

- The Committee elected Esther Werner as chairperson of the IWP for a 3-year mandate with 28 votes in favour (1 abstention).

E.6 Quality Working Party (QWP)

- The Committee discussed the revised guideline on the process validation for finished products: information and data to be provided in regulatory submissions (EMA/CHMP/CVMP/QWP/BWP/70278/2012-Rev1) and the overview of comments received. The guideline is foreseen for adoption at the December 2013 meeting of the CHMP and at the January 2014 meeting of the CVMP, for release for publication.
- The Committee discussed the revised guideline on stability testing for applications for variations to a marketing authorisation (EMA/CHMP/CVMP/QWP/441071/2011) and the overview of comments received (EMA/CHMP/CVMP/QWP/774027/2013). The guideline is foreseen for adoption in January 2014.
- The Committee discussed the revised Questions and Answers document on the limits for microbiological quality for premixes for medicated feeding stuffs which contain excipients of natural origin. The document is foreseen for adoption in January 2014.

- The Committee discussed the Questions and Answers documents on the stability of generics versus the innovator product.
- The Committee received a verbal report on the 69th Joint CHMP/CVMP QWP meeting held on 3-5 December 2013 and noted the agenda of the meeting.

E.7 Environmental Risk Assessment Working Party (ERAWP)

- The Committee discussed considerations regarding the ERAWP reflection paper on the environmental risk assessment of ivermectin.

E.8 Antimicrobials Working Party (AWP)

- The Committee considered the comments received from IFAH-Europe and from the FVE on the reflection paper on the use of pleuromutilins in food-producing animals in the European Union and agreed that the document needs to be further revised. As next step the AWP would consider these comments and prepare a draft revision of the reflection paper for consideration by the CVMP.
- The Committee received a verbal report from the AWP meeting held on 3 December 2013 and noted the agenda and draft minutes of the meeting.

E.9 Joint CVMP/CHMP AHEG on the application of the 3Rs (JEG 3Rs)

- The Committee received a verbal report from the vice chair of the JEG 3Rs on the meeting held on 3 October 2013.
- The Committee adopted the concept paper on review and update of EMA guidelines to implement best practice with regard to 3Rs (EMA/CHMP/CVMP/JEG-3Rs/704685/2012) for a 3-month period of public consultation.
- The Committee discussed the work undertaken by the JEG 3Rs in reviewing 3Rs compliance of batch release tests for centrally authorised veterinary vaccines and discussed the process for deciding which companies to contact.

E.10 Other working party issues

- There were no items for discussion.

The following documents were circulated for information:

- Minutes of the Scientific Advice Working Party meeting held on 5 November 2013.
- Agenda of the EWP-V meeting on 3-4 December 2013 and minutes of the EWP-V meeting held on 17-18 September 2013.
- Focus Group meeting on the revision of the CVMP guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances to be held on 9 December 2013: draft agenda, presentations and comments from interested parties.
- Final minutes of the 68th Joint CHMP/CVMP Quality Working Party meeting held on 25–27 September 2013.
- Summary record of the Joint meeting of the GMP/GDP Inspectors Working Group and CHMP/CVMP Quality Working Party meeting held on 25 September 2013.

F - SAFETY OF VETERINARY MEDICINES AND RESIDUES

F.1 Appointment of rapporteurs, co-rapporteurs and peer reviewers for the establishment of new MRLs

Information relating to letters of intent for new MRL applications cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee considered a request from the German Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) for revision of the MRL opinion on barium selenate and appointed rapporteurs and peer reviewers for the procedure.

F.2 Critical issues related to centralised procedures

Information on critical issues related to MRL centralised procedures cannot be released at the present time as it is deemed to be commercially confidential.

F.3 Other MRL items

Information on pending MRL-related issues cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee discussed a query on whether the MRL status for ketoprofen can be considered to apply to the S(+)-enantiomer and confirmed this to be the case.
- The Committee noted the published summary report from the 78th JECFA meeting held in Geneva on 5-14 November 2013.

F.4 Antimicrobial Resistance

- The Committee received a verbal report from the Antimicrobial advice ad hoc expert group (AMEG) meeting held on 26-27 November 2013 and noted the agenda and the draft minutes of the meeting.
- The Committee received a verbal report from the European Commission for advice on the impact on public and animal health of the use of antibiotics in animals and noted the draft agenda of the consultation meeting with stakeholders organised by the EMA on the request of the Commission which will take place on 28 February 2014.

F.5 Pharmacovigilance

- There were no items for discussion.

G - APPLICATIONS FOR GRANTING OF COMMUNITY MARKETING AUTHORISATIONS

G.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information relating to letters of intent to submit and eligibility requests concerning community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential.

G.2 Inspections

Information relating to GMP and Pharmacovigilance inspections will not be published as it would undermine the purpose of such inspections.

G.3 Regulatory issues

Information relating to certain regulatory issues on community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential.

G.4 Miscellaneous items

Information relating to certain miscellaneous items on community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential.

H – REQUEST FOR CLASSIFICATION AS MUMS/LIMITED MARKET

Information relating to availability of medicines cannot be released at the present time as it is deemed to be commercially confidential.

I - CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- The Committee received a verbal report from the chair of the CMDv on the meeting held on 7-8 November 2013. The draft minutes of the November 2013 meeting and the draft agenda of the meeting held on 12-13 December 2013 were circulated for information.

J - ORGANISATIONAL MATTERS

- The Committee noted the presentation given by the secretariat on the confidential and public mock-up versions of the November CVMP minutes in preparation for the publication of the CVMP minutes.
- The Committee noted the Table of actions following the November 2013 CVMP meeting.

K - LEGISLATION

- There were no items for discussion.

L - ANY OTHER BUSINESS

- The draft Press Release was circulated for members to provide any comments within 24 hours.

ANNEX I - List of participants and conflicts of interests identified for the December 2013 CVMP meeting

Country	CVMP Member	Restriction	Items on current agenda for which conflicts of interests have been identified*
CHAIR	**Anja Holm**	**Full involvement**	
AT	Barbara Zemann	Cannot act as rapporteur or peer reviewer on:	• A.2.2 Metacam & Novem (EMEA/V/C/000033/WS0473/G) (EMEA/V/C/000086/WS0473/G) • G.1 products • G.2 products • G.2 products
BE	Bruno Urbain	Full involvement	
BG	Damyan Iliev	Full involvement	
CZ	Jiří Bureš	Full involvement	
DE	Cornelia Ibrahim	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Irmeli Happonen	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Ljiljana Markuš-Cizelj	No part in discussions, final deliberations and voting as appropriate and cannot act as rapporteur on:	• A.2.1 (EMEA/V/C/002526/0000) • B. Panacur AquaSol (EMEA/V/C/002008/X/003) • C.5 Activyl Tick Plus • G.2 products
IE	David Murphy (vice-chair)	Full involvement	
IT	Maria Tollis	Full involvement	
LV	Zanda Auce	Full involvement	
MT	Stephen Spiteri	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
PT	João Duarte Da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stane Srčič	Full involvement	
SK	Judita Hederova	Full involvement	
UK	Helen Jukes	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	Christian Friis	Full involvement	
Co-opted	Boris Kolar	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
NO	Hans Kristian Østensen	Full involvement	

Country	CVMP Member	Restriction	Items on current agenda for which conflicts of interests have been identified*
IS	Jóhann Lenharðsson	Full involvement	

*Procedure number shown where applicable.

Country	CVMP alternate	Restriction	Items on current agenda for which conflicts of interests have been identified*
AT	Ines Lindner	Full involvement	
BE	Frédéric Klein	Full involvement	
DE	Esther Werner	Full involvement	
FR	Michael Holzhauser-Alberti	Full involvement	
HU	Tibor Soós	Full involvement	
NL	Peter Hekman	Full involvement	
NO	Hanne Bergendahl	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
UK	Anna-Maria Brady	Full involvement	

*Procedure number shown where applicable.

Country	European experts participating for specific agenda items	Items on current agenda for which conflicts of interests have been identified*	Restriction
	Maria Dominguez Nicolas	No restrictions were identified for the participation of the European experts attending the meeting for discussion on specific agenda items	
	Alan Fauconnier		
ES	Aranzazu Gonzalez-Canga		
ES	Amparo Lopez Rivera		
SE	Karolina Törneke		
UK	Ralph Woodland		
DE	Arne Hein (remotely)		
NL	Piet-Hein Overhaus (remotely)		
DE	Jens Schönfeld (remotely)		
UK	Ken Stapleton (remotely)		

*Procedure number shown where applicable.

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
ERAWP	Boris Kolar
EWP	Gesine Hahn

CVMP working parties and CMDv	Chair
IWP	Jean-Claude Rouby
PhVWP	Peter Ekström
SAWP	Rory Breathnach
CMDv	Esther Werner

Observer from the European Commission	
Karin Krauss	