9 September 2014
EMA/CVMP/557195/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 8-10 July 2014 meeting

Chair: A. Holm – Vice-chair: D. Murphy

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted 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 July 2014 meeting. In accordance with the Agency's revised policy and procedure on the handling of conflicts of interests, participants in this meeting were asked to declare any conflict of interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee Secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members – i.e. 22 or more members were present in the room. It was noted that 17 members were needed 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 the present time as it is deemed to be commercially confidential.

No contacts were declared.

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4. Adoption of the minutes of the previous meeting

The minutes of the June 2014 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 the 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 (28 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report for the establishment of MRLs in fin fish for **hexaflumuron** (EMEA/V/MRL/003802/FULL/0001). The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the report from the EU-RL, two peer review reports and the comments received from CVMP members.
- 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 extension of MRLs to porcine species for **gamithromycin** (EMEA/V/MRL/003158/EXTN/0002). The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the report from the EU-RL and a peer review report.
- 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 extension of MRLs to *Equidae* for **methylprednisolone acetate** (EMEA/V/MRL/002964/EXTN/0004). The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the report from the EU-RL and a peer review report.
- 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 extension of MRLs to eggs for **tylvalosin** (EMEA/V/MRL/003044/EXTN/0005). The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted two peer review reports.
- 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 the establishment of MRLs for **doxycycline** (EMEA/V/MRL/003660/EXTN/0003) in rabbits and the extrapolation of the maximum residue limits already established in bovine, porcine and poultry species, and now recommended in rabbits, to all food producing species. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the report from the EU-RL and a peer review report.
- 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 the establishment of final MRLs for **tulathromycin** (EU/12/199/PFZ) in bovine and porcine species, following the recommendation of provisional (amended) MRLs in October 2013. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the report from the EU-RL and a peer review report.

- The Committee adopted the CVMP scientific overview and list of questions for the establishment of MRLs in bovine species for a substance (EMEA/V/MRL/003988/FULL/0001), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur and two peer review reports.

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 (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Nobilis IB Primo QX** (EMEA/V/C/002802/0000), recommending the granting of the marketing authorisation. The product is a viral vaccine containing live avian infectious bronchitis virus for the active immunisation of chickens against respiratory disease (infectious bronchitis). The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

A.2.2 Variations to Community marketing authorisations

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality type II variation for **COXEVAC** (EMEA/V/C/000155/II/0006), recommending the variation of the marketing authorisation. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted the CVMP list of questions for a quality type II variation for **Easotic** (EMEA/V/C/000140/II/0006/G).
- The Committee adopted the CVMP list of questions for a type II variation for **NexGard** (EMEA/V/C/002729/II/0001), to change the SPC and the package leaflet due to new clinical data.
- The Committee adopted the CVMP list of questions for a type II variation for **Broadline** (EMEA/V/C/002700/II/0001), to add new indications for the target species cats.
- The Committee noted the letter from the MAH withdrawing their application for a type II variation for **AFTOVAXPUR DOE** (EMEA/V/C/002292/II/0002).

A.2.3 Re-examination of CVMP opinions

- There were no items for discussion.

A.2.4 Lists of questions

- The Committee adopted the scientific overview and benefit-risk assessment including the list of questions and agreed comments on the draft product information for a new product, (EMEA/V/C/003797/0000), a bacterial vaccine for pigs. The Committee noted two peer review reports and the comments received from CVMP members.

- The Committee adopted the scientific overview and benefit-risk assessment including the list of questions, the list of questions on the applicant's part of the ASMF and the restricted part of the ASMF, and agreed comments on the draft product information for a new cardiovascular product (EMEA/V/C/003836/0000) for dogs. The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview and benefit-risk assessment including the list of questions and agreed comments on the draft product information for a new anti-inflammatory product (EMEA/V/C/003866/0000) for horses. The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted the scientific overview and benefit-risk assessment including the list of questions and agreed comments on the draft product information for a new product (EMEA/V/C/003869/0000), a viral vaccine for chickens. The Committee noted two peer review reports and the comments received from CVMP members.

A.3 REFERRALS AND RELATED PROCEDURES

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- The Committee considered a request from Ceva Santé Animale to provide an oral explanation to the CVMP for the referral procedure for **Suanovil 20 and associated names, Captalin and associated names and generic products thereof** (EMEA/V/A/086) concerning the indications, dosage and withdrawal periods. The Committee agreed on the request and adopted a revised timetable for the procedure. The Committee also discussed the co-rapporteur's proposals for withdrawal periods for the concerned products. The oral explanation is scheduled for the September 2014 meeting of the Committee when the opinion will also be adopted.
- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **all veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to horses** (EMEA/V/A/104) related to indications, dosage and target animal safety, and noted four peer review reports. The Committee considered that there remained outstanding points where clarification was required, and adopted a list of outstanding issues to be addressed in writing by the applicants/marketing authorisation holders. The Committee agreed to a two month clock stop of the procedure and endorsed the revised timetable. The next discussion on the procedure is foreseen for the October 2014 meeting of the Committee.
- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **all veterinary medicinal products containing colistin to be administered orally** (EMEA/V/A/106) related to indications and prudent use warnings, and noted four peer review reports and the comments received from CVMP members. The Committee endorsed the draft CVMP assessment report to be sent to the applicants/marketing authorisation holders concerned for comments on the recommendations made. A two month period for comments is foreseen and the next discussion on the procedure is scheduled for the November 2014 meeting of the Committee.

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

- The Committee was informed of the formal notification from Boehringer Ingelheim Vetmedica GmbH of their decision to withdraw the type II variation application for **Ubrolexin intramammary suspension for lactating dairy cows** (*cephalexin, kanamycin*) (EMEA/V/A/102). Given the withdrawal, the Committee considered the procedure closed.

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

- The Committee was informed that following a meeting of the Standing Committee for medicinal products for veterinary use, held on 2 July 2014, the Standing Committee adopted the draft Commission Decision regarding the referral procedure for Fiprex spot-on solutions for cats and dogs (EMEA/V/A/099), in line with the CVMP recommendation.
- The Committee noted the background information for publication for the referral procedure for Fiprex spot-on solutions for cats and dogs (EMEA/V/A/099).

B. MARKETING AUTHORISATION APPLICATIONS FOR DISCUSSION AND DECISION

- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for a marketing authorisation application for a new haematological product for dogs (EMEA/V/C/002794/0000). The Committee discussed the draft product information and noted the two peer review reports received from CVMP members, and agreed to invite the applicant for an oral explanation in October 2014. The adoption of the opinion is foreseen for the November 2014 meeting of the Committee.
- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for a marketing authorisation application for a new viral and bacterial vaccine for pigs (EMEA/V/C/003796/0000). The Committee discussed the draft product information and noted the comments received from CVMP members. The adoption of the opinion is foreseen for the September 2014 meeting of the Committee.
- The Committee endorsed a list of candidates nominated and identified for the ad-hoc expert group for a new vaccine for Atlantic salmon (EMEA/V/C/002390/0000).
- The Committee noted the formal notification from **Nexcyon Pharmaceuticals Ltd** of their decision to withdraw the application for an initial marketing authorisation for a new hormonal product for cats, **Enthryv** (EMEA/V/C/002808/0000). More information about this application and the current state of the scientific assessment at the time of the withdrawal will be made available in a public assessment report.

C. POST-AUTHORISATION ISSUES (EXCLUDING VARIATIONS)

C.1 General issues

- There were no items for discussion.

C.2 Post-authorisation measures to CVMP opinions on the granting of Community marketing authorisations and annual reassessments

- The Committee adopted the rapporteur's recommendation assessment report for **ZOLVIX** (EMEA/V/C/000154).
- The Committee adopted the rapporteur's recommendation assessment report for **ZACTRAN** (EMEA/V/C/000129).

C.3 Product anniversary list

- The Committee noted the product anniversary list for the period between 06.06.2014 – 10.07.2014:

Product	Period
Circovac (EMEA/V/C/000114)	21.06.2013 – 20.06.2014
Convenia (EMEA/V/C/000098)	19.06.2013 – 18.06.2014
Equilis Prequenza (EMEA/V/C/000094)	08.07.2013 – 07.07.2014
Equilis Prequenza Te (EMEA/V/C/000095)	08.07.2013 – 07.07.2014
Equilis Te (EMEA/V/C/000093)	08.07.2013 – 07.07.2014
Equilis West Nile (EMEA/V/C/002241)	06.06.2013 – 05.06.2014
Equioxx (EMEA/V/C/000142)	25.06.2013 – 24.06.2014
Leucofeligen FeLV/RCP (EMEA/V/C/000143)	25.06.2013 – 24.06.2014
Leucogen (EMEA/V/C/000144)	17.06.2013 – 16.06.2014
Melovem (EMEA/V/C/000152)	07.07.2013 – 06.07.2014
MS-H vaccine (EMEA/V/C/000161)	14.06.2013 – 13.06.2014
Nobilis IB4-91 (EMEA/V/C/000036)	09.06.2013 – 08.06.2014
Porcilis ColiClos (EMEA/V/C/002011)	14.06.2013 – 13.06.2014
Porcilis Pesti (EMEA/V/C/000046)	09.06.2013 – 08.06.2014
Posatex (EMEA/V/C/000122)	23.06.2013 – 22.06.2014
Poulvac E. coli (EMEA/V/C/002007)	15.06.2013 – 14.06.2014
Prilactone (EMEA/V/C/000105)	20.06.2013 – 19.06.2014
Reconcile (EMEA/V/C/000133)	08.07.2013 – 07.07.2014
Suprelorin (EMEA/V/C/000109)	10.07.2013 – 09.07.2014

C.4 Renewals of marketing authorisations

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the renewal of **Aivlosin** (EMEA/V/C/000083/R/0059). The Icelandic CVMP member 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 for the renewal of **ZOLVIX** (EMEA/V/C/000154/R/0013).
- The Committee adopted a list of outstanding issues for the renewal of **Zulvac 8 Bovis** (EMEA/V/C/000145/R/0016).
- The Committee adopted a list of outstanding issues for the renewal of **Zulvac 8 Ovis** (EMEA/V/C/000147/R/0016).

C.5 Pharmacovigilance – PSURs and SARs

- The Committee endorsed the rapporteur's assessment report for **Pexion** (EMEA/V/C/002543), including the questions raised, to be forwarded to the MAH.
- The Committee discussed the post authorisation study protocol for **Parvoduk** (EMEA/V/C/002740) and endorsed the comments presented by the rapporteur to be forwarded to the MAH.
- 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 (EMEA/V/C/000163)	01.09.2013-28.02.2014
Bovilis BTV8 (EMEA/V/C/000148)	01.10.2013-31.03.2014
Coxevac (EMEA/V/C/000077)	01.04.2013-31.03.2014
Draxxin (EMEA/V/C/000077)	01.12.2010-30.11.2013
Emdocam (EMEA/V/C/002283)	01.09.2013-28.02.2014
Equilis Prequenza Te (EMEA/V/C/000095)	01.08.2013-31.01.2014
Equilis Prequenza (EMEA/V/C/000094)	01.08.2013-31.01.2014
Equilis StrepE (EMEA/V/C/000078)	01.08.2013-31.01.2014
Melosus (EMEA/V/C/002001)	01.09.2013-28.02.2014
Nobivac L4 (EMEA/V/C/002010)	01.08.2013-31.01.2014
Proteq West Nile (EMEA/V/C/002005)	01.09.2013-28.02.2014
Purevax Rabies (EMEA/V/C/002003)	01.09.2013-28.02.2014
RevitaCAM (EMEA/V/C/002379)	01.09.2013-28.02.2014
RHINISENG (EMEA/V/C/000160)	01.04.2013-31.03.2014
Semintra (EMEA/V/C/002436)	01.09.2013-28.02.2014
Zulvac 1 Bovis (EMEA/V/C/002334)	01.09.2013-28.02.2014

Product	Period
Zulvac 1 Ovis (EMEA/V/C/002335)	01.09.2013-28.02.2014

- The Committee endorsed the list of products and calendar for signal detection analysis.
- The Committee discussed the recommendations made by PhVWP-V concerning the surveillance of centrally authorised products and agreed to follow their proposals.

C.6 Supervisions and sanctions

- There were no items for discussion.

The following document was circulated for information:

- Status report on Periodic Safety Update Reports (PSURs) for centrally authorised veterinary medicinal products (EMA/CVMP/497281/2006)

D. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

D.1 VICH

- The Committee endorsed the EU comments on topic 3 - standards for effectiveness of the VICH Task Force on the revision of anthelmintic guidelines.
- The Committee received a verbal report on the VICH steering committee meeting held on 23-26 June 2014 in Brussels and noted the press release from the meeting.

D.2 Codex Alimentarius

- There were no items for discussion.

D.3 Other EU bodies and international organisations

- The Committee received an update on the progress of the EFSA Working Group working to recommend Reference Points for Action for chloramphenicol.

The following documents were circulated for information:

- Status of VICH guidelines and action plan of CVMP and working parties.
- VICH Task Force on the revision of the anthelmintic guidelines: topic 1 - adequacy of infection; follow-up question and responses from all regions.
- VICH Task Force on the revision of the anthelmintic guidelines: topic 2 - geometric means and blocking; FDA response to comments from regions.
- VICH EWG on Metabolism and Residue Kinetics: report from the VICH MRK EWG meeting held on 16-19 June 2014 in Brussels report from the EU expert.

E. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information relating to certain working parties topics discussed at this meeting cannot be released at the present time as it is deemed to be commercially confidential.

E.1 Scientific Advice Working Party (SAWP-V)

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

- The Committee received a verbal report from the chair of the SAWP-V on the meeting held on 8 July 2014, and noted the agenda of the meeting.

E.2 Pharmacovigilance Working Party (PhVWP)

- The Committee adopted the CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/10418/2009 – V.11) and the list of changes to the combined VeDDRA list of clinical terms: additional clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/PhVWP/377918/2014).
- The Committee adopted guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans (EMA/CVMP/PhVWP/288284/2007).
- The Committee received a verbal report from the chair of the PhVWP on the meeting held on 20-21 May 2014, and noted the draft minutes of the meeting.
- The Committee received a verbal report from the vice-chair of the PhVWP on the meeting held on 1-2 July 2014, and noted the draft agenda of the meeting.

E.3 Efficacy Working Party (EWP-V)

- The Committee adopted the guideline on the demonstration of palatability of veterinary medicinal products (EMA/CVMP/EWP/206024/2011) and the overview of comments received (EMA/CVMP/EWP/391535/2013). The new guideline will come into effect in February 2015.
- The Committee requested the EWP, supported by AWP, to review and update, if necessary, the question and answer document (EMA/CVMP/414812/2011) on the CVMP guideline on the SPC for antimicrobial products (EMEA/CVMP/SAGAM/383441/2005) in regard to the definition of “treatment and prevention” for antimicrobial substances.

E.4 Safety Working Party (SWP-V)

- The Committee received a verbal report from the chair of the SWP on the meeting held on 22-23 May 2014, and noted the agenda of the meeting.

E.5 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the chair of the IWP on the meeting held on 18-19 June 2014, and noted the draft minutes of the meeting.
- The Committee discussed the guideline on data requirements for changes to the strain composition of authorised equine influenza vaccines in line with OIE recommendations, and the overview of comments from the public consultation. The adoption of the guideline is foreseen for the September 2014 meeting of the Committee.

E.6 Quality Working Party (QWP)

- The Committee endorsed the re-election, by the CHMP at their June 2014 meeting, of Jean-Louis Robert as Chairperson of the Joint CHMP/CVMP Quality Working Party, for a further 3 year term.

E.7 Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the chair of the ERAWP on the meeting held on 17-18 June 2014 and the training of assessors held on 18-19 June 2014, and noted the draft minutes of the meeting.

E.8 Antimicrobials Working Party (AWP)

- The Committee adopted a concept paper proposing the development of a reflection paper on the use of aminoglycosides in animals in the European Union: development of resistance and impact on human and animal health (EMA/CVMP/AWP/158821/2014), for a 3-month period of public consultation. The proposed reflection paper will critically review recent information on the use of aminoglycosides in food producing and companion animals in the EU.
- The Committee received a verbal report from the chair of the AWP on the meeting held on 14-15 May 2014, 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 discussed the draft guideline on regulatory acceptance of 3Rs testing approaches (EMA/CHMP/CVMP/JEG-3Rs/450091/2012). The adoption of the guideline is foreseen for the September 2014 meeting of the Committee.

E.10 Other working party issues

- There were no items for discussion.

The following document was circulated for information:

- Minutes of the Scientific Advice Working Party meeting held on 3 June 2014.

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

F.2 Critical issues related to centralised procedures

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

- There were no items for discussion.

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.

F.4 Antimicrobial resistance

Information relating to antimicrobial resistance topics discussed at this meeting cannot be released at the present time as it is deemed to be confidential.

F.5 Pharmacovigilance

- The Committee saw a live demonstration of the new interface to query EVVET data.

The following document was circulated for information:

- The Consumer Voice in Europe (BEUC) Position Paper: Antibiotics use in livestock: Time to act

G. APPLICATIONS FOR GRANTING OF COMMUNITY MARKETING AUTHORISATIONS

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

Information concerning notifications of intent and eligibility requests relating to 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 be undermining 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.

- The Committee noted the EPAR module 6 scientific discussion for **Versican Plus Pi** (EMEA/V/C/003681/0000) concerning the granting of the initial marketing authorisation.
- The Committee noted the EPAR module 6 scientific discussion for **Versican Plus DHPPi** (EMEA/V/C/003679/0000) concerning the granting of the initial marketing authorisation.
- The Committee noted the EPAR module 6 scientific discussion for **Versican Plus L4** (EMEA/V/C/003680/0000) concerning the granting of the initial marketing authorisation.
- The Committee noted the EPAR module 6 scientific discussion for **Versican Plus Pi/L4** (EMEA/V/C/003683/0000) concerning the granting of the initial marketing authorisation.
- The Committee noted the EPAR module 6 scientific discussion for **Versican Plus Pi/L4R** (EMEA/V/C/003682/0000) concerning the granting of the initial marketing authorisation.
- The Committee noted the EPAR module 6 scientific discussion for **Osurnia** (EMEA/V/C/003753/0000) concerning the granting of the initial marketing authorisation.
- The Committee noted the EPAR module 6 scientific discussion for **Draxxin** (EMEA/V/C/000077/X/0026) concerning the extension of the initial marketing authorisation.

H. AVAILABILITY OF MEDICINES and MUMS classification

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

- The Committee discussed the draft revised policy for classification and incentives for veterinary medicinal products indicated for MUMS/limited market (EMA/308411/2014) and the draft guidance on the classification of veterinary medicinal products indicated for MUMS/limited market (EMA/CVMP/388694/2014). The guidance document will be revised in light of the comments made by members. The endorsement/adoption of the documents is foreseen for the September 2014 meeting of the Committee for a 6-week public consultation of the guidance document.

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

- The Committee received a verbal report from the chair of the CMDv for the the meeting held on 5-6 June 2014, and noted the draft minutes of the meeting as well as the draft agenda of the meeting held on 10-11 July 2014.

J. ORGANISATIONAL MATTERS

- The Committee was invited to propose further topics for the draft agenda of the Presidency meeting of the CVMP and joint CVMP/CMDv, to be held on 22-23 September in Rome, Italy. The adoption of the final agenda of the meeting is foreseen for the September 2014 meeting of the Committee.
- The Committee endorsed the secretariat's proposal for a revised structure for the CVMP agenda. The revised agenda will come into effect from the September 2014 meeting of the Committee onwards.
- The Committee received an update on the revised EMA policy on the handling of declarations of interests of scientific committees' members and experts.
- The Committee received induction training for the new EMA premises.

K. LEGISLATION

- There were no items for discussion.

L. ANY OTHER BUSINESS

- The Committee was informed on potential issues or procedures that would require CVMP decision(s) via written procedure during August 2014. The secretariat confirmed that there will be a single mailing on 29 July and the deadline for comments and objections will be for 6 August.
- Upon the completion of the July 2014 CVMP meeting, the draft press release was circulated for members to provide any comments within 24 hours.

ANNEX I - List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the July 2014 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**Anja Holm**	**Full involvement**	
AT	Barbara Zemann	Cannot act as rapporteur or peer reviewer for:	• C.5 Semintra, Pexion
BE	Bruno Urbain	Full involvement	
BG	Damyan Iliev	Full involvement	
CZ	Jiří Bureš	Full involvement	
DE	Cornelia Ibrahim	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Irmeli Happonen	Full involvement	
FR	Michael Holzhauser-Alberti	Full involvement	
HR	Ljiljana Markuš-Cizelj	No part in discussions, final deliberations and voting as appropriate, and cannot act as rapporteur for:	• A.2.1 Nobilis IB Primo QX (EMEA/V/C/002802/0000) • A.2.4 (EMEA/V/C/003869/0000) • A.2.4 (EMEA/V/C/003836/0000) • B. (EMEA/V/C/003796/0000) • C.5 Activyl, Bovilis BTV8, Equilis Prequenza, Equilis Prequenza-Te, Equilis StrepE, Nobivac L4
HU	Gábor Kulcsár	Full involvement	
IE	David Murphy (vice-chair)	Full involvement	
IT	Maria Tollis	Full involvement	
LU	Marc Schmit	Involvement in discussions only and cannot act as rapporteur for:	• A.1.1 Gamithromycin (EMEA/V/MRL/003158/EXTN/0002) • A.2.2 Broadline (EMEA/V/C/002700/II/0001) • A.2.2 NexGard (EMEA/V/C/002729/II/0001) • A.2.4 (EMEA/V/C/003836/0000) • A.3.3 Suanovil-Captalin (EMEA/V/A/086) • C.2 Zolvix, Zactran • C.4 Zolvix (EMEA/V/C/000154/R/0013) • C.5 Parvoduk PASS • C.5 Proteq West Nile, Purevax Rabies • G.3 one item

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
LV	Zanda Auce	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	
IS	Jóhann Lenharðsson	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
BE	Frederic Klein	Full involvement	
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
NL	Peter Hekman	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
UK	Anna-Maria Brady	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
* Experts were only evaluated against the topics they have been invited to talk about.			
BE	Sandy Vermout *(remotely)*	Full involvement	
DE	Uta Wolfinger *(remotely)*	Full involvement	
FR	Nathalie Bridoux *(remotely)*	Full involvement	
FR	Sylvie Louet	Full involvement	
NL	Baukje Schat *(remotely)*	Full involvement	
UK	Rory Cooney *(remotely)*	Full involvement	
UK	Sharon Reynolds	Full involvement	
UK	Noel Joseph	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
UK	Jean-Paul Schmidt	Full involvement	

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
ERAWP	Boris Kolar
EWP	Gesine Hahn
IWP and CMDv	Esther Werner
PhVWP	Peter Ekström *(remotely)*
QWP	Jean-Louis Robert *(remotely);* Piet-Hein Overhaus *(Vet vice chair - remotely)*
SAWP	Rory Breathnach

Observer from the European Commission	
Present	

European Medicines Agency support
Meeting run with relevant support from the EMA staff