8 July 2014
EMA/CVMP/415698/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 3-5 June 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 the addition of the topic of the Presidency meeting agenda under J items.

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 June 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 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 18 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.

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No contacts were declared.

4. Adoption of the minutes of the previous meeting

The minutes of the May 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 (29 members present of those eligible to vote) the CVMP opinion, including the EPMAR, and the CVMP assessment report recommending the extension of the time period applying to the provisional MRLs for **eprinomectin** (EU/10/173) in ovine and caprine species. The provisional MRLs for eprinomectin in ovine and caprine species expire on 1 July 2014 and a two year extension is now recommended. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the report from the EU-RL, a peer review report, the comments received from CVMP members and the summary opinion for publication.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion, including the EPMAR, and the CVMP assessment report recommending the extension of MRLs for **tulathromycin** (EMEA/V/MRL/003262/EXTN/0003) to ovine species and the extrapolation to caprine species. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary opinion for publication.
- The Committee adopted the CVMP scientific overview and list of questions for the establishment of MRLs in honey for a substance (EMEA/V/MRL/003923/FULL/0001), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur, two peer review reports, and the comments received from CVMP members and from EFSA.
- The Committee discussed the rapporteurs assessment report, the peer review report and the EU-RL report for the extension of MRLs to Equidae for a substance (EMEA/V/MRL/002964/EXTN/0004), and agreed that a list of questions was not necessary. The adoption of the opinion is foreseen for the July 2014 meeting of the Committee.
- The Committee discussed the rapporteur's assessment report, the rapporteur's assessment of the responses to the list of questions, the rapporteur's EPMAR and a peer review report for the extension of MRLs to rabbits for a substance (EMEA/V/MRL/003660/EXT/0003). The adoption of the opinion is foreseen for the July 2014 meeting of the Committee.
- The Committee discussed the rapporteur's assessment report, the rapporteur's EPMAR and a peer review report for the extension of MRLs to pigs for a substance (EMEA/V/MRL/003158/EXT/0002). The adoption of the opinion is foreseen for the July 2014 meeting of the Committee.

- The Committee discussed the rapporteur's assessment report, the rapporteur's EPMAR, two peer review reports and the EU-RL report for the establishment of MRLs in fin fish for a substance (EMEA/V/MRL/003802/FULL/0001). The adoption of the opinion is foreseen for the July 2014 meeting of the Committee.
- The Committee discussed the rapporteur's assessment report for the modification of ADI and MRLs for a substance (EU/12/199), and agreed that an oral explanation would not be necessary. The adoption of the opinion is foreseen for the July 2014 meeting of the Committee.
- The Committee adopted the CVMP scientific overview and list of questions for the review of the previous opinion for the establishment of MRLs for **diflubenzuron** (EMEA/V/MRL/003135/MODF/0003) in salmonidae, following the request from the European Commission under Article 11 of Regulation (EC) No. 470/2009 in view of recent evaluations by ECHA and EFSA and concerns relating to the genotoxic potential of the metabolite 4-chloroaniline. The Committee noted a peer review report and the comments received from CVMP members. In the context of this review, the Committee agreed to invite all interested parties (in particular the pharmaceutical industry, learned societies, governmental institutions, and EU and EEA-EFTA Member States) through a public call for data to submit any relevant scientific data, which may be used in the review.
- The Committee noted the request from the European Commission to review, under Article 11 of Regulation (EC) No. 470/2009, the MRLs established in all food producing species for **potassium selenate, sodium selenate and sodium selenite**. The secretariat reported on the appointment of a rapporteur and a co-rapporteur by written procedure. The Committee agreed on the proposed timetable and assessment approach. The adoption of the opinion is scheduled for the November 2014 meeting of the Committee.

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 (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **OSURNIA** (EMEA/V/C/003753/0000), recommending the granting of a marketing authorisation. The product is a fixed combination ear gel containing terbinafine, florfenicol and betamethasone for dogs. 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 **Versican Plus L4** (EMEA/V/C/003680/0000), recommending the granting of a marketing authorisation. The product is a bacterial vaccine containing inactivated leptospiras for dogs. 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 **Versican Plus Pi/L4** (EMEA/V/C/003683/0000), recommending the granting of a marketing authorisation. The product is a viral and bacterial vaccine containing live attenuated parainfluenza virus and inactivated leptospiras for dogs. 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 **Versican Plus Pi/L4R** (EMEA/V/C/003682/0000), recommending the granting of a marketing authorisation. The product is a viral and bacterial vaccine containing live attenuated parainfluenza virus, inactivated leptospiras and inactivated rabies virus for dogs. The Icelandic and Norwegian CVMP members 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 the CVMP list of questions for a worksharing type IB quality variation for **Circovac, Eurican Herpes 205, Ibraxion, Purevax RCPCh, Purevax RCPCh FeLV, Purevax RCCh and Vaxxitek HVT+IBD** (EMEA/V/C/000xxx/WS/0546).
- The Committee adopted the CVMP list of questions for a type II quality variation for **COXEVAC** (EMEA/V/C/000155/II/0006).
- The Committee adopted the CVMP list of questions for a type II variation for **Zuprevo** (EMEA/V/C/002009/II/0006/G), to add a new therapeutic indication and delete a precautionary statement due to new target animal safety data.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a type II quality variation for **ProteqFlu** (EMEA/V/C/000073/II/0014), 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 type II quality variation for **ProteqFlu-Te** (EMEA/V/C/000074/II/0017), recommending the variation of the marketing authorisation. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee noted the letter from the MAH withdrawing their application for a type II variation for **Profender** (EMEA/V/C/000097/II/0024) to change the legal status of Profender spot-on solution for cats from prescription-only medicine to non-prescription.

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 antiparasitic product (EMEA/V/C/003842/0000). The Committee noted a peer review report 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 the notification from the European Commission for a referral procedure under Article 35 of Directive 2001/82/EC for **all veterinary medicinal products containing colistin to be administered orally**, in order to give its opinion on the measures that need to be taken to ensure the prudent use of colistin in food-producing animals across the EU and to minimise potential risks with the use of the identified products. The Committee agreed to start a referral procedure (EMEA/V/A/106) under Article 35 and appointed C. Ibrahim as rapporteur and M. Holzhauser-Alberti as co-rapporteur for the procedure. The Committee endorsed a 120-day timetable for the procedure with no clock stop at the start of the procedure. The discussion of the rapporteur's assessment report including the co-rapporteur's critique is foreseen for the July 2014 meeting of the Committee. The Committee noted the discussion document on the background and issues for referral, and the list of products concerned.

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 discussed the rapporteur's assessment report and its annex for the referral procedure for **Resflor injectable solution for cattle** (EMEA/V/A/101), and considered the request from the marketing authorisation holder for an oral explanation. The Committee considered that there remained outstanding points where clarification was required, and adopted a list of outstanding issues to be addressed by the marketing authorisation holder in writing and at the oral explanation. The oral explanation is scheduled for the September 2014 meeting of the Committee. The Committee adopted a revised timetable and noted the peer review reports and the comments received.
- The Committee discussed the rapporteur's assessment report, including the co-rapporteur's critique, for the referral procedure for **Ubrolexin intramammary suspension for lactating dairy cows** (EMEA/V/A/102) and noted the peer review reports. The Committee adopted a list of outstanding issues, to be addressed in writing by the marketing authorisation holder, and a revised timetable.

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

- The Committee endorsed the CVMP response to the question raised by EDQM that has arisen from the CVMP opinion concerning the Article 30(3) procedure for **dapsone** (EMEA/V/A/075) in respect to the dapsone impurity levels in sulfonamides.

- The Committee discussed the revised rapporteur's assessment report and the risk management considerations proposed for the Article 30(3) procedure for **lidocaine** (EMEA/V/A/092).

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 received an oral explanation from the applicant concerning an application for a new hormonal product (EMEA/V/C/002808/0000) for cats. The Committee also discussed the draft product information and the rapporteur's assessment of the responses to the list of outstanding issues. The adoption of the opinion is foreseen for the July 2014 CVMP meeting.
- The Committee received an oral explanation from the applicant concerning an application for a new product (EMEA/V/C/002802/0000), a viral vaccine for chickens. The Committee also discussed the draft product information. The adoption of the opinion is foreseen for the July 2014 CVMP meeting.

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 **Versican Plus DHPPi+L4** (EMEA/V/C/003678).
- The Committee adopted the rapporteur's recommendation assessment report for **Versican Plus DHPPi+LR4** (EMEA/V/C/002759).
- The Committee adopted the rapporteur's recommendation assessment report for **NexGard** (EMEA/V/C/002729).

C.3 Product anniversary list

- The Committee noted the product anniversary list for the period between 09.05.2014 – 05.06.2014:

Product	Period
Naxcel (EMEA/V/C/000079)	19.05.2013 – 18.05.2014
Improvac (EMEA/V/C/000136)	11.05.2013 - 10.05.2014

C.4 Renewals of marketing authorisations

- The Committee adopted a list of outstanding issues for the renewal of **Aivlosin** (EMEA/V/C/000083/R/0059).

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the renewal of **Palladia** (EMEA/V/C/000150/R/0007). The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. It was agreed that the authorisation should now be indefinite.

C.5 Pharmacovigilance – PSURs and SARs

- 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
ECOPORC SHIGA (EMEA/V/C/002588)	01.08.2013-31.01.2014
Equilis Te (EMEA/V/C/000093)	01.02.2013-31.01.2014
Gonazon (WD) (EMEA/V/C/000075)	01.02.2011-31.01.2014
Kexxtone (EMEA/V/C/002235)	01.08.2013-31.01.2014
Melovem (EMEA/V/C/000152)	01.02.2013-31.01.2014
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01.03.2013-28.02.2014
Onsior (EMEA/V/C/000127)	01.01.2013-31.12.2013
ProZinc (EMEA/V/C/002634)	12.07.2013-31.01.2014
Rheumocam (EMEA/V/C/000121)	01.08.2013-31.01.2014
Suprelorin (EMEA/V/C/000109)	01.08.2013-31.01.2014
Trifexis (EMEA/V/C/002635)	19.04.2013-04.01.2014
Zulvac 8 Bovis (EMEA/V/C/000154)	01.08.2013-31.01.2014
Zulvac 8 Ovis (EMEA/V/C/000145)	01.08.2013-31.01.2014

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

C.6 Supervisions and sanctions

- There were no items for discussion.

The following document was circulated for information:

- Status report on PSURs for centrally authorised veterinary medicinal products.

D. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

D.1 VICH

- The Committee endorsed the draft EU comments on topic 1 and topic 2 of the VICH Task Force: revision of anthelmintic guidelines.
- The Committee noted the final EU response to the questionnaires to collect information on combination products in regions for the VICH Task Force on Efficacy Studies for Combination Products further to the discussion at the May 2014 CVMP meeting.
- The Committee noted the comments received from interested parties during the public consultation in the EU on the draft VICH guideline on bioequivalence (VICH GL52).

- The Committee noted the final EU comments on draft 2 of the VICH Metabolism and Residue Kinetics guideline on Residue studies in fish and draft 2 of the guideline, as well as the further comments provided from CVMP members in preparation of the VICH EWG meeting on 16-19 June 2014 in Brussels.
- The Committee noted the draft agenda for the 30th VICH Steering Committee meeting to be held on 23-26 June 2014, in Brussels.
- The Committee discussed the VICH document on the future vision from Industry on a globally harmonised pharmacovigilance system to be discussed at the 30th VICH Steering Committee meeting.

D.2 Codex Alimentarius

- There were no items for discussion.

D.3 Other EU bodies and international organisations

Information relating to topics discussed under point D.3 at this meeting cannot be released at the present time as it is deemed to be confidential.

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-V)

Information relating to SAWP-V 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 3 June 2014, and noted the agenda of the meeting.

E.2 Pharmacovigilance Working Party (PhVWP-V)

- The Committee noted the agenda and the minutes of the meeting held on 25-26 March 2014, and deferred the verbal report from the chair of the PhVWP-V on the meeting held on 20-21 May 2014 to the July 2014 meeting of the Committee.

E.3 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the chair of the EWP-V on the meeting held on 13-14 May 2014.

E.4 Safety Working Party (SWP-V)

- There were no items for discussion.

E.5 Immunologicals Working Party (IWP)

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

E.6 Quality Working Party (QWP)

- The Committee received a verbal report from the vice-chair of the QWP on the meeting held on 13-15 May 2014, and noted the agenda of the meeting and also the agenda of the interested parties meeting held on 15 May 2014.
- The Committee adopted the revised overview of comments on the guideline on stability testing for applications for variations to a marketing authorisation, following consideration of comments from received from EGGVP.

E.7 Environmental Risk Assessment Working Party (ERAWP)

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

E.8 Antimicrobials Working Party (AWP)

- The Committee noted the agenda and the draft minutes of the meeting and deferred the verbal report from the chair of the AWP on the meeting held on 14-15 May 2014 to the July 2014 meeting of the Committee.

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

- The Committee adopted the concept paper proposing the development of a guideline on transferring methods validated in collaborative trials to a product/laboratory specific context, for a three month consultation period. The paper will be published once it has been adopted by CHMP.

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 6 May 2014.
- Agenda of the EWP-V meeting held on 13-14 May 2014 and draft minutes.
- Draft agenda of the SWP-V meeting held on 22-23 May 2014.
- Final Minutes of the 70th joint CHMP/CVMP QWP meeting held on 4–6 February 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.

- The Committee considered the request for the inclusion of **benzethonium chloride** in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009, and agreed to its inclusion as an excipient in the list.
- The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009).
- The Committee briefly discussed the comments received during the public consultation on the reflection paper on injection site residues. These will be further discussed once additional feedback has been received from residue control authorities.

F.4 Antimicrobial resistance

- The Committee noted the agenda and the draft minutes of the meeting, and deferred the verbal report from the chair of the AMEG on the meeting held on 15-16 May 2014 to the July 2014 meeting of the Committee.
- The Committee received a verbal report from the secretariat on the meeting 'EC Working group on antimicrobial resistance' held on 21 May 2014 in Brussels.

F.5 Pharmacovigilance

- There were no items for discussion.

The following document was circulated for information:

- The website of the newly started European project, the EFFORT (Ecology from Farm to Fork Of microbial drug Resistance and Transmission): www.effort-against-amr.eu.

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.

- The Committee discussed the eligibility requests and appointment of rapporteurs and peer reviewers and updates concerning intended applications and offers to act as rapporteur, co-rapporteur and peer reviewer and agreed the appointments.

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 endorsed the EPAR module 6 scientific discussion for **Versican Plus DHPPi/L4** (EMEA/V/C/003678/0000).
- The Committee endorsed the EPAR module 6 scientific discussion for **Versican Plus DHPPi/L4R** (EMEA/V/C/002759/0000).

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.

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

- The Committee received a verbal report from the chair of the CMDv for the meetings held on 10-11 April and on 7-8 May, and noted the draft minutes of the meeting held on 7-8 May 2014 and the draft agenda of the meeting held on 5-6 June 2014.

J. ORGANISATIONAL MATTERS

- The Committee discussed the document prepared by the secretariat on multinational assessment teams for CVMP procedures further to the initial discussion at the April 2014 CVMP meeting.
- The Committee received a verbal report from the chair on the Strategic Planning Group meeting held on 4 June 2014 and noted the agenda of the meeting and the draft minutes of the previous meeting.
- The Committee received a verbal report on the upcoming Presidency meetings of CVMP and CMDv, to be held on 22-23 September in Rome, Italy. A draft agenda of the meeting will be presented for discussion at the July 2014 CVMP meeting.
- The Committee received a presentation on the upcoming move of the Agency.

K. LEGISLATION

- There were no items for discussion.

L. ANY OTHER BUSINESS

- Upon the completion of the June 2014 CVMP meeting, the draft press release was circulated for members to provide their 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 June 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:	• A.3.5 Ubrolexin (EMEA/V/A/102) • C.5 ProZinc
BE	Bruno Urbain	Full involvement	
BG	Damyan Iliev	Full involvement	
CY	Alia Michaelidou Patsia	Full involvement	
CZ	Jiří Bureš	Full involvement	
DE	Cornelia Ibrahim	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	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.2.2 Zuprevo (EMEA/V/C/002009/II/0006/G) • A.3.5 Resflor (EMEA/V/A/101) • B. EMEA/V/C/002802 • C.5 Gonazon, Equilis Te, Nobilis Influenza H5N2 • G.2 one item
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 Eprinomectin (EU/10/173/) • A.1.1 EMEA/V/MRL/003158/EXTN/0002 • A.2.1 Osurnia (EMEA/V/C/003753/0000) • A.2.2 WS0546, Proteq Flu (EMEA/V/C/000073/II/0014), Proteq Flu-Te (EMEA/V/C/000074/II/0017) • A.2.4 EMEA/V/C/003842/0000 • A.3.3 Colistin (EMEA/V/A/106) • C.2 NexGard • C.5 Onsior • G.2 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	
NL	Johan Schefferlie	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	Cannot act as rapporteur or peer reviewer for:	• A.3.3 Colistin (EMEA/V/A/106)
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	Cannot act as rapporteur or peer reviewer for:	
Co-opted	Boris Kolar	Cannot act as rapporteur or peer reviewer for:	• A.3.3 Colistin (EMEA/V/A/106)
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
DE	Esther Werner	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
NO	Tonje Høy	Full involvement	
PL	Anna Wachnik-Święcicka	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.			
DK	Niels Kyvsgaard	Full involvement	
ES	Javier Alonso Naveda *(remotely)*	Full involvement	
ES	Ricardo Carapeto Garcia *(remotely)*	Full involvement	
UK	Katherine Healey *(remotely)*	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	Sam Fletcher *(remotely)*	Full involvement	
UK	Rory Cooney	Full involvement	

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
ERAWP	Boris Kolar
EWP	Gesine Hahn
IWP and CMDv	Esther Werner
SAWP	Rory Breathnach

Observer from the European Commission	
Present	

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