11 March 2014
EMA/CVMP/149513/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Minutes of the 210th CVMP meeting of 11-13 February 2014

Committee for Medicinal Products for Veterinary Use (CVMP)

The meeting was chaired by A. Holm.

Note on access to documents

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 February 2014 meeting, see Annex I. 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 the present time as it is deemed to be commercially confidential.

4. Adoption of the minutes of the previous meeting

The minutes of the January 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.

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A. ADOPTION OF OPINIONS/LIST OF QUESTIONS

A.1 ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

A.1.1 Opinions on applications

- The Committee adopted the CVMP scientific overview and list of questions for the establishment of MRLs for chickens for a substance (EMEA/V/MRL/003878/FULL/0001), following discussion of the rapporteur's assessment report with the co-rapporteur's critique, 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 (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Parvoduk** (EMEA/V/C/002740/0000), recommending the granting of a marketing authorisation. The product is a vaccine for ducks containing a live attenuated duck parvovirus. 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 discussed the CVMP opinion and the CVMP assessment report for a type II variation for **Profender** (EMEA/V/C/000097/II/0024), concerning the change in legal status of Profender spot-on solution for cats. A list of outstanding issues would be discussed at the March CVMP meeting. The Committee also noted the comments received from CVMP members.

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped type II quality variation for **Profender** (EMEA/V/C/000097/II/0025/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 the CVMP list of questions for a type II variation for **Cerenia** (EMEA/V/C/000106/II/0022), concerning the extension of the duration of the use of Cerenia tablets.

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 cardiovascular product (EMEA/V/C/003786/0000) for use in cats. 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 psycholeptic product (EMEA/V/C/003764/0000) for use in dogs. The Committee noted two peer review reports.

A.3 REFERRALS AND RELATED PROCEDURES

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

- The Committee adopted a timetable for a re-examination of the December 2013 CVMP opinion 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). The Committee agreed to the request from the marketing authorisation holder, Vet-Agro Trading Sp. z o.o., to provide an oral explanation at the March 2014 CVMP meeting. The adoption of the final CVMP opinion and CVMP assessment report is foreseen for the April 2014 meeting of the Committee.

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

- The Committee discussed the updated rapporteur's assessment report following responses to the list of outstanding issues and the draft product information for the referral procedure for **Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names** (EMEA/V/A/091). The Committee considered that there remained outstanding points where clarification was required, and adopted a second list of outstanding issues to be addressed in writing by the marketing authorisation holder and a revised timetable.

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

- The Committee considered the request from the applicant and marketing authorisation holders for an extension of the clock stop for the referral procedure for **all veterinary medicinal products containing altrenogest to be administered orally to pigs and horses** (EMEA/V/A/095). The Committee agreed to a one year clock stop on the basis that the marketing authorisation holders would provide a tailored environmental risk assessment, and adopted a revised timetable.

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 considered the notification from the reference Member State, France, for a referral procedure for **Resflor solution injectable** due to concerns expressed by Germany and Denmark regarding the efficacy of the product against the proposed new target pathogen *Mycoplasma bovis*. The Committee agreed to start a referral procedure (EMEA/V/A/101) under Article 13 and appointed C. Ibrahim as rapporteur and M. Holzhauser-Alberti as co-rapporteur for the procedure. The Committee adopted a list of questions and a timetable. The adoption of the CVMP opinion and CVMP assessment report is foreseen for the July 2014 meeting of the Committee.
- The Committee considered the notification from the reference Member State, Ireland, for a referral procedure for **Ubrolexin intramammary suspension for lactating dairy cows** (EMEA/V/A/102), due to concerns raised by the Czech Republic relating to the extended duration of treatment for mastitis caused by *Staphylococcus aureus*. The Committee agreed to

start a referral procedure under Article 13 and appointed J. Bureš as rapporteur and D. Murphy as co-rapporteur for the procedure. The Committee adopted a list of questions and a timetable. The adoption of the CVMP opinion and CVMP assessment report is foreseen for the July 2014 meeting of the Committee.

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 noted a letter from the European Commission for a Standing Committee meeting.

The following document was circulated for information:

- Referrals tracking table.

B. MARKETING AUTHORISATION APPLICATIONS FOR DISCUSSION AND DECISION

- The Committee discussed a request from the applicant for an extension of the timeframe for the submission of the responses to the list of questions for a marketing authorisation application for a new product (EMEA/V/C/002590). The Committee agreed on the need for a more detailed justification from the applicant to enable the decision.
- The Committee agreed to a request from the applicant for an extension of the timeframe for the submission of the responses to the list of questions for a marketing authorisation application for a new product (EMEA/V/C/002794), and endorsed a revised timetable.
- The Committee adopted the mandate of an ad-hoc expert group (AHEG) to be consulted in the assessment of the marketing authorisation application for a new product (EMEA/V/C/002390), to provide expert advice on specific issues raised by the CVMP and which are addressed in the list of questions. The advice would be requested once the applicant's responses to these issues have been assessed by the rapporteurs. The request for advice will be formulated in a specific list of questions.

C. POST-AUTHORISATION ISSUES (EXCLUDING VARIATIONS)

C.1 General issues

- The Committee adopted the list of veterinary medicinal products to be included in the 2015 sampling and testing programme.

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

- 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 the annual reassessment

of **BTVPUR AlSap 2-4** (EMEA/V/C/000139/S/0004), recommending the conversion of the marketing authorisation to normal status for this product as the specific obligations for the product are now fulfilled. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

C.3 Product anniversary list

- The Committee noted the product anniversary list for the period between 17 January 2014 – 13 February 2014:

Product	Period
Comfortis (EMEA/V/C/002233)	11.02.2013-10.02.2014
Dicural (EMEA/V/C/000031)	16.01.2013-15.01.2014
Fevaxyn Pentofel (EMEA/V/C/000030)	05.02.2013-04.02.2014
Gripovac 3 (EMEA/V/C/000157)	14.01.2013-13.01.2014
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	27.01.2013-26.01.2014
Ingelvac CircoFLEX (EMEA/V/C/000126)	13.02.2013-12.02.2014
Kexxtone (EMEA/V/C/002235)	28.01.2013-27.01.2014
Loxicom (EMEA/V/C/000141)	10.02.2013-09.02.2014
Meloxidyl (EMEA/V/C/000115)	15.01.2013-14.01.2014
Nobilis OR Inac (EMEA/V/C/000062)	24.01.2013-23.01.2014
Pirsue (EMEA/V/C/000054)	29.01.2013-28.01.2014
Porcilis PCV (EMEA/V/C/000135)	12.01.2013-11.01.2014
RESPIPORC FLU3 (EMEA/V/C/000153)	14.01.2013-13.01.2014
Semintra (EMEA/V/C/002436)	13.02.2013-12.02.2014
STARTVAC (EMEA/V/C/000130)	11.02.2013-10.02.2014
TruScient (EMEA/V/C/002000)	14.12.2012-13.12.2013
ZULVAC 8 Bovis (EMEA/V/C/000145)	15.01.2013-14.01.2014
ZULVAC 8 Ovis (EMEA/V/C/000147)	15.01.2013-14.01.2014

- The Committee noted the following corrections in the product anniversary list from the January meeting:

Product	Period
Activyl Tick Plus (EMEA/V/C/002234)	09.01.2013-08.01.2014
BTVPUR AlSap 1 (EMEA/V/C/002230)	17.12.2012-16.12.2013
BTVPUR AlSap 1-8 (EMEA/V/C/002231)	17.12.2012-16.12.2013
CORTAVANCE (EMEA/V/C/000110)	09.01.2013-08.01.2014

Product	Period
Metacam (EMEA/V/C/000033)	07.01.2013-06.01.2014
Onsior (EMEA/V/C/000127)	16.12.2012-15.12.2013
Prac-Tic (EMEA/V/C/000103)	18.12.2012-17.12.2013
ProMeris (EMEA/V/C/000107)	19.12.2012-18.12.2013
ProMeris Duo (EMEA/V/C/000108)	19.12.2012-18.12.2013
Rheumocam (EMEA/V/C/000121)	10.01.2013-09.01.2014
Ypozane (EMEA/V/C/000112)	11.01.2013-10.01.2014

C.4 Renewals of marketing authorisations

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and CVMP assessment report for the renewal of **Improvac** (EMEA/V/C/000136/R/0024). 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 by consensus (29 members present of those eligible to vote) the CVMP opinion and CVMP assessment report for the renewal of **Equilis StrepE** (EMEA/V/C/000078/R/0010). 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.

C.5 Pharmacovigilance – PSURs and SARs

- The Committee agreed on recommendations for improvement of the post-authorisation safety study protocol from the marketing authorisation holder for **Trifexis** (EMEA/V/C/002635), taking into account the comments received from the rapporteur, the PhVWP and the CVMP members.
- The Committee adopted the CVMP assessment report on the PSUR for the period 01.02.13 - 31.07.13 for **Suprelorin** (EMEA/V/C/000109) and concluded that amendments to the product information were required to provide further clarification and include reference to the frequency of an existing adverse reaction already on the product information.
- 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
BLUEVAC BTV8 (EMEA/V/C/000156)	01.05.2013-30.10.2013
Bovilis BTV8 (EMEA/V/C/000148)	01.04.2013-30.09.2013
CaniLeish (EMEA/V/C/002232)	01.04.2013–30.09.2013
Comfortis (EMEA/V/C/002233)	01.10.2012-31.03.2013
ECOPORC SHIGA (EMEA/V/C/002588)	09.01.2013-31.07.2013
Ibraxion (EMEA/V/C/000051)	01.10.2010-30.09.2013

Product	Period
Netvax (EMEA/V/C/000134)	01.05.2013-30.10.2013
Nobivac Myxo-RHD (EMEA/V/C/002004)	01.04.2013-31.09.2013
ZULVAC 1+8 Bovis (EMEA/V/C/002473)	01.04.2013-30.09.2013
ZULVAC 1+8 Ovis (EMEA/V/C/002251)	01.04.2013-30.09.2013

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

C.6 Supervisions and sanctions

- There were no items for discussion.

The following document was circulated for information:

- Status report on periodic safety update reports (PSURs) for centrally authorised veterinary medicinal products.

D. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

D.1 VICH

- The Committee considered a request from IFAH Europe for an anthelmintic focus group meeting in the context of the VICH considerations to revise the existing VICH guidelines and agreed that the EWP will discuss this request and consider holding such a meeting. The matter will be further discussed at the March 2014 meeting of the Committee.
- The Committee endorsed the revised draft VICH GL on the Harmonization of criteria to waive target animal batch safety testing for live vaccines for veterinary use and considered the comments from other regions on the last draft VICH GL.
- The Committee adopted the VICH GL 53 on Electronic exchange of documents: file format requirements (EMA/CVMP/VICH/758781/2013) for release for consultation at step 4 of the VICH process.

D.2 Codex Alimentarius

- There were no items for discussion.

D.3 Other EU bodies and international organisations

- The Committee discussed a request from EFSA for cooperation on establishing “Reference Points for Actions (RPAs) for non-allowed pharmacologically active substances present in food of animal origins” in relation to **nitrofurans** and appointed N. Joseph as the EMA/CVMP representative to the EFSA group.

The following document was circulated for information:

- Status of active VICH Guidelines and action plan of CVMP and working parties.

E. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

E.1 Scientific Advice Working Party (SAWP)

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

- The Committee received a verbal report from the chair of the SAWP on the meeting held on 11 February 2014, and discussed the agenda of the meeting.

E.2 Pharmacovigilance Working Party (PhVWP)

- The Committee received a verbal report from the chair of the PhVWP on the meeting held on 28-29 January 2014, and noted the agenda and the draft minutes of the meeting.
- The Committee discussed the veterinary pharmacovigilance public bulletin 2013. The bulletin will be circulated for final adoption at the March 2014 meeting of the Committee.

E.3 Efficacy Working Party (EWP)

- The Committee re-elected Gesine Hahn as chair of EWP for a further 3-year mandate.

E.4 Safety Working Party (SWP)

- There were no items for discussion.

E.5 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the secretariat of the IWP on the meeting held on 4-5 February 2014, and noted the agenda and the draft minutes of the meeting. The Committee also noted the minutes of the meeting held on 1-2 October 2013.
- The Committee adopted the revised IWP Work Plan 2014 (EMA/CVMP/IWP/535960/2013) for publication.

E.6 Quality Working Party (QWP)

- The Committee received a verbal report from the vice-chair of the Joint CHMP/CVMP QWP on the meeting held on 4-6 February 2014, and noted the agenda.
- The Committee discussed the revised guideline on the use of near infrared spectroscopy (NIRS) by the pharmaceutical industry and the data requirements for new submissions and variations, the addendum and the overview of comments. The guideline is foreseen to be adopted at the March 2014 meeting of the Committee.
- The Committee discussed a concept paper on the withdrawal of the note for guidance on development pharmaceutics and the establishment of a guideline on the selection of sterilisation process for drug products. The concept paper is foreseen to be adopted at the March 2014 meeting of the Committee.
- The Committee discussed the guidance template for the Qualified Person (QP) declaration, and the overview of comments received. The documents are foreseen to be adopted at the March 2014 meeting of the Committee.
- The Committee discussed the question and answer document on limits for unspecified impurities in veterinary medicinal products. The document is foreseen to be adopted at the March 2014 meeting of the Committee.

- The Committee discussed and agreed on a request to the EDQM to consider the development of a Ph. Eur. monograph for florfenicol.

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 28-29 January 2014 and noted the agenda and the draft minutes of the meeting. The Committee also noted the minutes of the meeting held on 1-2 October 2013.
- The Committee endorsed the programme for the assessor training on environmental risk assessment focussing on the fate of veterinary medicinal products in the environment, scheduled for 18-19 June 2014.

E.8 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the chair of the AWP on the meeting held on 22-23 January 2014 and noted the agenda and the draft minutes of the meeting.
- The Committee endorsed the further revised reflection paper on the use of pleuromutilins in food-producing animals in the European Union: development of resistance and impact on human and animal health, and the further revised overview of comments received.

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

- There were no items for discussion.

E.10 Other working party issues

- There were no items for discussion.

The following documents were circulated for information:

- Minutes of the SAWP meeting held on 14 January 2014.
- Agenda of the EWP meeting to be held on 18-19 February 2014.
- Final Minutes of the 69th Joint CHMP/CVMP QWP meeting held on 3–5 December 2013.
- Minutes of the ERAWP meeting held on 1-2 October 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.

- There were no items for discussion.

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

- The Committee received a verbal report from the secretariat on the antimicrobial advice ad hoc expert group (AMEG) meeting held on 23-24 January 2014, and noted the agenda and the draft minutes of the meeting. The Committee noted the revised agenda of the consultation meeting with the stakeholders on the request from the European Commission for advice on the impact on public and animal health of the use of antibiotics in animals.
- The Committee received a verbal report from the secretariat on the ESVAC annual network meeting and the stakeholders meeting held on 4-5 February 2014 and noted the agendas of the annual network meeting, the ESVAC expert group meeting and the stakeholders meeting.
- The Committee noted the preliminary agenda of the Working Group Antimicrobial Resistance meeting organised by DG SANCO in Brussels on 11 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 concerning letters 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 agreed to the transfer of rapporteurship for Bravecto from P. Hekman to J. Schefferlie.
- The Committee agreed to the transfer of all co-rapporteurship and peer reviewer responsibilities from T. Soós to G. Kulcsár.

G.2 Inspections

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

- There were no items for discussion.

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.

- The Committee discussed the draft document on the clarification of the applicability of the MUMS policy in respect to products for horses along with the written comments received. An updated document was presented at the meeting, which will be discussed again at the March 2014 CVMP meeting. The Committee also received an update on the ongoing review of the MUMS policy and agreed that the project plan for the completion of the work will be presented at the March 2014 meeting of the Committee. The annual report and review of the MUMS scheme for 2013 will be presented to CVMP prior to adoption by the EMA Management Board in March 2014.

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

- The Committee noted the draft minutes of the meeting held on 16-17 January 2014 and the draft agenda of the meeting held on 13-14 February 2014.

J. ORGANISATIONAL MATTERS

- The Committee adopted the minutes of the informal CVMP meeting and the joint CVMP/CMDv meeting, held on 21-23 October 2013 in Vilnius, Lithuania, and noted the recommendations from the meeting. The CVMP work plan will be updated accordingly and will be brought back for adoption at the March CVMP meeting.
- The Committee agreed that J. P. Duarte da Silva would participate in the HMA Task Force on adaptation of timetables in procedures.
- The Committee discussed the draft programme of the EMA/IFAH-Europe Info Day to be held on 13-14 March 2014.
- The Committee received a verbal report from the chair of the Strategic Planning Group (SPG) on the meeting held on 12 February 2014. The main discussion focused on the recommendations made at the informal CVMP and joint CVMP/CMDv meeting in Vilnius, Lithuania. The chair also noted that the end-of-year questionnaire of the PhVWP was a useful exercise and encouraged the chairs of the other CVMP working parties to consider a similar exercise. The Committee noted the agenda and the minutes of the meeting held on 11 September 2013, and the next SPG meeting, which is scheduled for June 2014.
- The Committee noted the first announcement/invitation to the CVMP Interested Parties' meeting to be held on 7 May 2014, and the draft minutes of the previous meeting, held on 15 May 2013.
- The Committee received a presentation on the Agency's move to its new premises in July 2014.

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 February 2014 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 for:	• A.3.5 Ubrolexin (EMEA/V/A/101)
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	
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.3.5 Resflor (EMEA/V/A/102) • C.4 Equilis StrepE (EMEA/V/C/000078/R/0010) • C.5 Bovilis BTV8, Netvax, Nobivac Myxo • G.1 two products
IE	David Murphy (vice-chair)	Full involvement	
IT	Maria Tollis	Full involvement	
LU	Marc Schmit	No part in discussions, final deliberations and voting as appropriate, and cannot act as rapporteur for:	• A.2.1 Parvoduk (EMEA/V/C/002740/0000) • C.2 BTVPUR AlSap 2-4 (EMEA/V/C/000139/S/0004) • C.5 Ibraxion • E.1 one product • G.1 four products
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	

Country	CVMP Member	Restriction	Items on current agenda for which conflicts of interests have been identified*
Co-opted	Christian Friis	Full involvement	
Co-opted	Boris Kolar	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
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*
BE	Frédéric Klein	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	
HU	Tibor Soós	Full involvement	
NL	Peter Hekman	Full involvement	
NO	Hanne Bergendahl	Full involvement	
PL	Anna Wachnik-Święcicka	Cannot act as rapporteur or peer reviewer for:	• A.2.2 Profender (EMEA/V/C/000097/II/0024 and EMEA/V/C/000097/II/0025/G) • A.3.2 Baytril (EMEA/V/A/091)
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	Restriction	Items on current agenda for which conflicts of interests have been identified
BE	Michel Goret *(remotely)*	No restrictions were identified for the participation of the European experts attending the meeting for discussion on specific agenda items	
BE	Bart Hoet *(remotely)*		
ES	Raul Belmar Liberato *(remotely)*		
ES	Gema Cortes Ruiz *(remotely)*		
ES	Maria Dominguez Nicolas *(remotely)*		
ES	Arancha Gonzalez Canga *(remotely)*		
ES	Rafael Ortega Huedo *(remotely)*		

Country	European experts participating for specific agenda items	Restriction	Items on current agenda for which conflicts of interests have been identified
SE	Karl Ljungvall		

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
ERAWP	Boris Kolar
EWP	Gesine Hahn
IWP and CMDv	--
PhVWP	Peter Ekström *(remotely)*
QWP	Piet-Hein Overhaus *(remotely)*
SAWP	Rory Breathnach

Observer from the European Commission	
Present	